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**KIDNEYCENTERS**

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TO: Department of Health and Human Services  
Centers for Medicare and Medicaid Services

FROM: Northwest Kidney Centers (NKC)  
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DATE: May 1, 2005

FILE CODE: CMS-3818-P: Conditions for Coverage for End Stage Renal Disease Facilities

The Northwest Kidney Centers (NKC) is pleased to be able to provide CMS with comments regarding the proposed changes in regulations for the End Stage Renal Disease Program. NKC is a not-for-profit, community-based organization that provides dialysis services to the Greater Puget Sound Area in the State of Washington, servicing approximately 1200 patients on both in-center and home-dialysis.

This document provides some general comments regarding the new Conditions of Coverage (C of C) and some specific areas that need further consideration for change.

The shift away from process requirements to a more patient-centered C of C is good although several places in the C of C appear to be very prescriptive and more process focused than patient focus. Thus these requirements may be unattainable by facilities and therefore makes them contrary to this particular goal.

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In a number of cases the C of C appears to hold facilities responsible for activities and results over which they have no control. This would require facilities to focus more on process and monitoring than on the more positive patient centered focus.

Home dialysis has been recognized as having positive outcomes for patients. Much more attention needs to be paid to this portion of the C of C and better definition of regulations to reflect the differences between hemodialysis and peritoneal dialysis as home therapies.

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NKC applauds the use of the Centers for Disease Control, AAMI, DOQI, and AIA standards as CMS is recognizing the expertise of these organizations. There are some concerns about using the recommendations of these organizations exclusively as they do not recognize the differences between home dialysis versus in-center. Some of the AIA standards for the building of dialysis facilities are of concern e.g. 1 sink at every 4-dialysis stations is very prohibitive in cost and very excessive for the needs of dialysis

facilities. AAMI does not address home dialysis for water purification at all. How will the C of C stay current as those referent authorities change recommendations?

NKC would like to thank CMS for the opportunity to provide comments on the C of C for End Stage Renal Disease Patients. We hope these comments add some clarity to the issues outlined and add some very specific examples where the terms of the regulations need further review and clarification

If you need any further clarification on the comments provided please feel free to contact Connie Anderson, Clinical Services Director, at 206-292-2771 ext. 4871 or via e-mail [connie@nwkidney.org](mailto:connie@nwkidney.org).

Specific comments relating to the regulations:

**III A. Definitions (Proposed 494.10)**

The C of C should expand the definition for "home dialysis" to include ALL living arrangements that are considered the patient's permanent residence. The definition of "home dialysis" needs to include both hemodialysis and peritoneal dialysis although the needs are very different between the 2 modalities.

**IV. A. Infection Control (Proposed 494.30)**

Regulations propose to direct the reporting relationship for the Infection Control Safety Officer. NKC has no concerns that this position should require the expertise and skills of at least a nurse but Conditions become prescriptive when they define the reporting relationships. This should be for the facilities to determine what is the best reporting mechanism.

**IV.B. Water Quality (Proposed 494.40)**

It is good that the Conditions do not incorporate ultra-pure dialysate as there is still not enough evidence-based data to support incorporating ultra-pure dialysate into the regulations. This requires further research and specific standards/criteria will need to be established.

**(Proposed 494.40 (c))**

The AAMI Standards do not consider the needs of the home hemodialysis patient for water treatment. As written the current standards would cause home hemodialysis programs to close due to the costs of doing weekly testing for newly installed home patients and/or monthly bacteria levels. The Conditions must separate out water purity standards for the home patients different than facility testing since home patients have a single water source and single machine purifying the water.

**(Proposed 494.40 (c)(2))**

NKC believes that chlorine testing should be done before each patient shift and not based on number of hours. Regulations should not define the points of testing since this becomes very prescriptive and increases monitoring processes and costs.

*CMS has asked for comments on regarding the requirements for water quality regarding the AAMI standards for carbon tanks. NKC feels that the current AAMI standards of 10 minutes of empty bed contact time should be ample to meet any potential safety and health issues.*

#### **IV. C. Reuse of Hemodialyzers and Bloodlines (Proposed 494.50)**

Within the preamble is a statement on pg.51 that "dialysis facilities that fail to follow the reuse protocol will be subject to denial of participation in the Medicare program..." This statement should be removed from the regulations as it creates such a threat to dialysis facilities that it might force going to single use dialyzers at tremendous cost to organizations. This is the only place in the Conditions with such a statement.

#### **D. Physical Environment (Proposed 494.60)**

NKC firmly believes that the proposed regulations regarding emergencies should not be as restrictive as to require specific emergencies and natural disasters be spelled out in the regulations. (494.60(d) pg. 58-59

#### **V. Proposed Part 494 Subpart C (Patient Care)**

##### **A. Patient's Rights (494.70)**

NKC firmly believes that a patient should have information about Advanced Directives and make a personal decision about the use of the Directives. 494.70(a)(5) pg. 74 states that this would be a requirement in the patients' rights condition. The regulations need to be more explicit in stating that they must be presented to patients as a choice but patients are not required to determine their Directives. The language as stated in the regulations is unclear as to what CMS intended.

All facilities have extensive policies. In (494.70)(a)(7) the conditions require that patients be informed of the facilities patient care policies including isolation. This is an overwhelming, unnecessary, and burdensome requirement for the patients. The regulations should make sure that patients have access to facility policies versus the facilities required to provide them to patients. In (494.70)(a)(10), NKC strongly objects to the requirement that patients be fully informed about charges not covered by Medicare. This is not information that care-giving staff neither has access to nor can answer questions about and it changes often based on individual circumstances. Trained and informed staff should explain non-covered charges. This Condition referencing charges should be deleted.

##### **B. Patient Assessments (494.80)**

In the Conditions the definition of the team does not explicitly include the Medical Director. We suggest that the referenced "nephrologist" could be the Medical Director or the treating nephrologist.

NKC supports the concept of the Patient Assessment and agree with the minimum elements of that Assessment. We disagree with the 20-day time frame that is proposed.

## **B. Patient Assessments**

### **(494.80)(b)(1) and (2)**

New patients are unstable and frequently hospitalized. We believe that this requirement would be better defined as number of **consecutive treatments** versus calendar days or a period of 2-3 months. We also firmly believe that the reassessment should not occur within a 3-month time frame but should occur no earlier than 6 months. The regulations appear to be very confusing in the category. It is unclear how the patient assessments coordinate with the monthly unstable care plans. Are patients "unstable" if they have not met the goals that are established during the assessment and plan of care? If so then the monthly care plan for unstable patients would put a tremendous burden on the facilities. The Conditions need to better state the regulations regarding the different categories of Assessment.

## **C. Patient Plan of Care (Proposed 494.90)**

*NKC is happy that CMS is eliminating in 494.90 the need for the patient long-term program. NKC also agrees with the change in Conditions to eliminate the transplant surgeon from signing the patients' plan of care*

### **1. Developing the Patient Plan of Care (Proposed 494.40)**

NKC is pleased that the new regulations will be based on best practices and outcomes through the DOQI guidelines. However, due to the nature of the ESRD population, not all patients will be able to achieve 100% of the DOQI recommended outcomes. Patients with ESRD have many reasons why they do not achieve outcomes from changing medical condition to psychological reasons. It is an unnecessary burden for facilities to make adjustments on a temporary basis. The Condition should encourage facilities to meet or exceed the standards but not be so restrictive that it states ALL patients – there must be a risk factor adjustment.

### **(494.90)(a)(2)**

CMS has invited comments on the proposed nutritional guidelines for outcome measures. On pg. 93 the Conditions use anthropometrics measurements for nutritional status. Anthropometrics measurements are no longer used by Nutritionists, Subjective Global Assessments (SGA's) have taken their place and incorporate a much more comprehensive assessment of the patient. NKC would encourage CMS to look at SGA's as an alternative. We do not recommend CMS to add any additional specific nutritional requirements.

### **d. Vascular Access (Proposed 494.90(a)(4))**

NKC agrees that there should be a vascular access component to the plan of care but it should not include "evaluation of the hemodialysis patient for the appropriate vascular

access type.” This would be the responsibility of the nephrologist in conjunction with the surgeon – not the facility. This language should be removed from the regulations.

**e. Transplant Status (Proposed 494.90(a)(5))**

NKC feels very strongly that facilities should not be responsible for the tracking and plan of care for the transplant referral. The actions listed in the Conditions should not be the responsibility of the facilities. This is better met by the Regulations governing the Transplant Centers Conditions of Coverage (484.94(c) Patient Records)(3) This language should be removed from the regulations.

**f. Rehabilitation Status (Proposed 494.90(a)(6))**

NKC readily approves of the focus on rehabilitation but is concerned that CMS in their annual assessment of patient rehabilitation only considers taxable work and school as valued rehabilitation markers; homemakers have been a forgotten entity and truly show a sign of rehabilitation. We also agree that active participation in rehabilitation is the key to success but to include rehabilitation into a “distinct plan of care” puts the facility in a situation that is unattainable. Facilities should not be held accountable for the rehabilitation of patients since that is so highly individualized but should be accountable for referrals to outside agencies that potentially could assist patients. This is outside the scope of renal facilities and could potentially put a financial burden on the facility that they are unable to meet. There are no monies available to dialysis facilities to provide a host of services such as physical, occupational, and recreational therapies and no monies available to patients to pay for such services. This needs to be removed from the regulations. CMS must consider the cost to facilities to incorporate this into the patients’ treatment prescription pg.101 etc. NKC does not disagree that patients should be referred to appropriate agencies but we do take exception that CMS has an outcome-based requirement for rehabilitation in the plan of care.

**2. Implementation of the Patient Plan of care (Proposed 494.90(b))**

It is contrary to CMS’s goal of being less restrictive to put a 10-calendar day time frame for the Patient Plan of Care to be signed by the patient and implemented. This is unrealistic, as many patients may not dialyze all treatments within the 10 calendar days. CMS should consider changing this regulation to reflect number of consecutive dialyses e.g. 13. CMS has asked for comments regarding time frames. Calendar-days is not an appropriate measure as many new patients may be hospitalized after initial dialysis and are very unstable. Prescribing a time frame is very restrictive and will be unattainable in most cases for facilities to meet. This is also true for non-English speaking patients where interpreters are necessary to schedule in order to set the Plans of Care.

**494.80(d)**

CMS proposes that the “interdisciplinary team must adjust and sustain the specified patient outcome goals.” This is not achievable 100% of the time as patient risk factors and co-morbidities would impact achieving this regulation. This language needs to be removed from the regulations’ as it is very restrictive.

**494.90(b)(4)**

**494.90(b)(4)**

It is not the role of the facility, and out of our control to ensure that all patients are seen by a physician at least monthly and periodically in center. CMS has other mechanisms for encouraging this behavior. It is too restrictive also to require that facilities police whether physicians have written progress notes and/or sent office notes. Also the requirement cannot be applied to home patients as written. NKC strongly objects to this Condition and it should be deleted from the regulations. Physicians must document their encounters with patients via another mechanism and the facilities should not be held accountable for this activity. This includes the regulation that facilities are held accountable for office notes/progress notes – it should be removed, as facilities should not be held accountable for physicians. Physicians' visits should not be included in the Conditions of Coverage for facilities.

**3. Transplant Referral Tracking (Proposed 494.90(c))**

The dialysis facility should not be held accountable for transplant referral status once the referral has been made by the nephrologist. This condition should be deleted. The responsibility should be with the transplant center as proposed in the **Transplant Conditions of Coverage (494.94(c). Patient records (3).** Facilities can assist in the process by drawing blood but should not be held accountable for the transplant workup process and status.

**D. Condition: Care at Home (Proposed 494.100)**

NKC as one of the largest home dialysis facilities in the country strongly objects to the language in **494.100(a)** where the interdisciplinary team is responsible for providing "self dialysis" training to the home patients. In our 43-year history this has not been necessary and this language should be removed from the regulations. NKC does not believe that the Conditions should require the training nurse to be an R.N. but believe that training for both PD and Home Hemodialysis could be accomplished by an LPN. Personnel requirements should only state that the Manager of the Home Dialysis Programs be a Registered Nurse.

**494.100(C)(1)(v)**

The AAMI recommendations were never intended for home hemodialysis. It is not acceptable to hold the home requirements to the same standard as the in-center facilities. CMS must understand that what is needed for the home is very different than what is required for in-center dialysis. We agree that the quality of water should be monitored but NOT at the same frequencies as in-center.

**D. Care at Home**

The specific level of hemoglobin and hematocrit needs to be removed and instead reference evidence based standards.

**494.100(c)2**

CMS has asked for comments on the requirement that suppliers report to the facility every 30 days all services and items furnished needs to be removed. Supplies may be sent to patient for more than 30 days and therefore this regulation becomes very

restrictive and not appropriate. It is important that facilities do know when suppliers are not able to meet a delivery and substitute products although not the routine orders and supplies. It would be more appropriate for CMS to regulate that suppliers must notify a facility when work is done on equipment either as service or as preventative maintenance in the home setting.

## **2. Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities**

CMS has requested comments on doing dialysis in a Nursing Home or Skilled Nursing Facility. CMS must recognize that this definition is too narrow. Many patients reside in a variety of home setting from adult family homes to assisted living to nursing homes. As long as it is the patients' permanent residence it should not matter where the dialysis occurs. NKC is VERY support of providing home dialysis, either peritoneal or hemodialysis, in any of the mentioned settings. The regulations need to reflect that these settings already have regulations governing dialysis patients and should not put any additional burden on dialysis facilities. Home dialysis can be carried out very safely in these settings with the appropriate training of the caregiver and/or staff. Dialysis facilities have no control over the care provided in these settings and should not be held accountable for the nursing care. The regulations should also reflect that a patient may not be competent to provide self-care and therefore may be exempt from the requirement. A patient caregiver would be trained to do the dialysis just like the home setting and the nursing home would have the responsibility for the rest of the care of the patient. An agreement (memorandum of understanding) that delineates the responsibilities between the facility and the nursing home would be all that is required. **It is imperative that CMS recognize that there is a difference between peritoneal and hemodialysis and the regulations should reflect this difference.**

### **c. Nursing Coverage (Proposed 494.180(b)(2))**

The proposed regulations that a Registered Nurse be on premise is very restrictive and not appropriate. (Previous regulations allowed either an RN or LPN.) The language appears to be inconsistent in the regulations between licensed professionals, which could rather be an RN or LPN versus a RN only. This regulation does not belong in the ESRD Conditions of Coverage but would be better place with the nursing home regulations. The ESRD facility should NOT be responsible for supplying RN coverage to the Nursing Home.

CMS is also requesting comments on the ratio of patient to caregiver assignment in the home setting. At most times it is a 1:1 ratio for hemodialysis, it is not true for peritoneal.

### **e. Monitoring**

Trained caregivers do not need to be in the room at all times in particular for PD patients. This statement should be removed from the regulations and/or clarify that it refers to hemodialysis only.

*As CMS is requesting comments on this entire section it is in the experience of NKC that almost everyone can be train anyone to do home hemodialysis regardless of their*

*background. Regulations should not specify the requirements for a home dialysis care giver regardless of the setting.*

The renal facility should not have a medical record requirement in the nursing home. That requirement should be part of the nursing home regulations.

#### **Special Purpose Renal Facility (494.120) Physician Contact**

In an emergency it may not be possible to contact the physician prior to initiating dialysis. The regulation should be modified to indicate that emergency Standing Orders or the patients' current orders may be followed until the physician is contacted.

#### **E. Quality Assessment and Performance Improvement Program**

CMS is on target to require patient satisfaction surveys. NKC believes there is more value to the organization to have an individualized survey that targets specific facility questions than to have a global national survey. The regulation should only require that a survey be done and within specified intervals.

#### **4. Facility Specific Standards for Enforcement**

CMS is asking for comments on the "feasibility of using commonly agreed upon clinical standards in requirements and enforcement efforts." NKC believes that the DOQI guidelines are evidenced based and have gained national acceptance. We do however have difficulty in the language that ALL patients must achieve these goals. That is not a realistic expectation and facilities cannot be held accountable for all patients.

**This would be an unnecessary regulatory burden on facilities.** It would be imperative that CMS consider risk adjustment factors that leads to a process burden as well and contrary to CMS's goal to reduce burden to the facilities.

#### **VI Personnel Qualifications (Proposed 494.140)**

##### **3. Dietitian (Proposed 494.140 (c))**

Requirements now state this must be an RD. The Conditions should not limit the coverage to RD's but should also include DTR's in the staff mix. DTR's have educational requirements similar to the RD's and are nationally certified. NKC strongly supports that the Conditions include the use of DTR's under the supervision of an RD.

##### **494.140(e)(1)**

NKC supports CMS in their dialysis technician minimal requirements. We would like to see the language in the regulation changed to include the use of LPN's in training dialysis technicians. NKC has no problem with the 3-month technician experience as long as the language is less restrictive to both LPN and RN as supervisor of the training.

#### **6. Other Personnel Issues**

Most dialysis facilities do not have pharmacists on staff. CMS has invited comment as to the role of a pharmacist and their services. This would be a tremendous burden for



facilities to provide pharmacy oversight and should be left out of the regulations since patients receive prescriptions from many different sources.

**B. Condition: Responsibilities of the Medical Director (Proposed 494.150)**

The Conditions assign responsibilities at the Unit level to the Medical Director. This is very restrictive and confusing for organization that have more than one facility, therefore more than one Medical Director that is under the direction of a Chief Medical Officer (CMO). Therefore the development, review, and approval of policies are made at the corporate level, not at the Unit level and this language should be removed from the regulations.

**D. Condition: Medical Records (494.170)**

**494.170 (d)**

Requiring that ALL medical records be copied and sent within 1 working day is unreasonable. NKC would propose that within 1 week is reasonable and doable. Normally records are transferred to the receiving facility before the patient is accepted for treatment that is the normal operating procedures. To accomplish the copying of records within 1 working day puts a burden on the dialysis facilities. This should be change in the Conditions.

**3. Governance Condition (Proposed 494.180)**

**Pg 186 of preamble**

The Conditions preamble states that Washington State requires 2 RN's/shift and a three to one patient to staff ratio. There are no such provisions in the State of Washington and those statements should be removed. Regulations should not mandate staffing ratios/patterns regardless of an acuity-based system or not. This would be very restrictive for dialysis facilities and Medicare surveyors. NKC strongly opposes this proposal to the regulations.

**494.180(b)(2)**

Requiring that an RN be present at all times contradicts with earlier regulations that LPN's can act as charge and are responsible for care. Regulations must be consistent in their approach otherwise it is very hard to interpret and understand the intent and meaning of the regulations.

**494.180.(b)(5)(i) through (viii)**

NKC strongly support CMS in the technician training criteria. It is imperative that dialysis technicians have the skills and expertise to take care of and understand the needs of the dialysis patient.

NKC would like to thank CMS for the opportunity to provide comments on the Conditions of Coverage for End Stage renal Disease Patients. We hope these comments add some clarity to the issues outlined and add some very specific examples where the term of the regulations need further review and clarification.

As stated previously, if you need any further clarification on the comments provided please feel free to contact Connie Anderson @ 206-292-2771 ext. 4871 or e-mail [connie@nwkidney, org](mailto:connie@nwkidney.org).



California Dialysis Council

May 2, 2005

The Honorable Mark McClellan  
 Administrator  
 Attention: CMS-3818- P  
 Centers for Medicaid and Medicaid Services  
 U.S. Department of Health and Human Services  
 Room 445-G  
 Hubert H. Humphrey Building  
 200 Independence Avenue, SW  
 Washington, DC 20201

**Re: CMS-3818-P Comments on Notice of Proposed Rulemaking on Conditions for Coverage for End Stage Renal Disease Facilities**

Dear Dr. McClellan:

The California Dialysis Council (CDC) welcomes the opportunity to comment on this very important NPRM regarding the proposed revisions to the End Stage Renal Disease Conditions for Coverage.

The CDC is a non-profit, voluntary, statewide organization representing the dialysis providers and patients in the state of California.

The CDC supports the fundamental shift in the proposed conditions for coverage from a focus on procedural standards to a focus on the patient's experience in the care delivery setting and on patient outcomes. However, we believe it is essential to appropriately fund the requirements, recommendations and quality improvement criteria. We acknowledge that a number of National Associations will be providing comments, so our focus has been to address only those of significant importance to the patients and providers in California.

California Dialysis Council comments on the proposed changes in the Conditions for Coverage for ESRD Facilities.

**Delineation of Responsibility (70 Fed. Reg. at 6212-14)**

In the preamble of the Proposed Rule, CMS has requested comment on how to address the issues raised concerning provision of dialysis to the elderly residing in Nursing Facilities (NF) and Skilled Nursing Facilities (SNF). We suggest that CMS clarify that, until the agency provides more nursing facility specific guidance, the institution in which the patient is living (e.g., a nursing or skilled nursing facility) will be deemed to be the patients' "home" for purposes of ESRD regulations.

The proposed regulations state "home hemodialysis services provided in a NF or SNF should be provided under the direction of a *certified dialysis facility that is responsible for the dialysis care provided to the ESRD patients, for assuring that the NF or SNF is capable of providing pre and post dialysis care and for assuring that there is coordination of care between the two entities....*"

There must be coordination of care and communication between both members of the care delivery team (i.e. dialysis facility and NF/SNF) and, in this regard, the current requirement for a written document describing the relationship between the two parties should suffice. Home hemodialysis with non-medical "helpers" has been in existence for over 30 years. Once a home dialysis helper has been trained by a dialysis provider certified to provide home dialysis training and support services, it should be irrelevant whether the home dialysis is provided in a patient home or a NF/SNF.

**Water Quality (Proposed § 494.40)**

*Chlorine/chloramines (Proposed § 494.4(c) (2) (ii) (A))*

If the test results are greater than 0.10 mg/L for chloramines as specified in paragraph (c)(2)(i), immediate termination of dialysis need not be the only alternative to protect patients. Some facilities use the addition of ascorbic acid to their acid concentrate to accommodate the removal of chlorine/chloramines from the water should the primary and secondary carbon tanks become exhausted.

We recommend a change in regulatory wording to state: Immediately terminate dialysis treatment to protect patients from exposure to chlorine/chloramines, **OR**, for facilities that add ascorbic acid to their acid concentrates, should there be breakthrough exceeding the limit of 0.1 mg/L of chlorine or chloramine at the secondary carbon tanks, the ascorbic acid policy having been implemented, the dialysate from each acid bath in use should be tested for the concentration of chlorine/chloramines. If the level of this test exceeds the limit of 0.1 mg/L then immediately terminate dialysis treatment.

**Patient Safety (Proposed §494.30)**

*Infection Control (Proposed §494.30(b)(2))*

The standard for oversight would designate a Registered Nurse as the infection control or safety officer for the ESRD facility. Under current Conditions, this is the responsibility of the Medical Director. In the proposed conditions, the Medical Director "is responsible for the delivery of patient care and patient outcomes in the facility." Additionally, the current Conditions require that the Medical Director ensure that staff in the unit are adequately trained and ensure the development of patient care policies and procedures and these responsibilities would be carried over in the new Conditions. Finally, in the new conditions the facility's QAPI program would be the operational responsibility of the Medical Director. Since the Medical Director maintains responsibility in all of the areas that impact infection control, we believe the tracking and trending of infections should remain a function of the QAPI process, under the direction of the Medical Director.

**Physical Environment** (Proposed §494.60)

*Emergency Equipment and Plans (Proposed §494.60(d)(3))*

You have requested comment regarding small rural ESRD facilities and the potential for an exemption from the requirement for an AED or other defibrillator. Under the assumption that a small rural facility is potentially some distance from emergency medical care and under the circumstance that every airport and commercial aircraft in this country as well as many retail stores have AED access, it seems inconceivable that a healthcare facility would not. We believe that there should be no exemption from the delivery of safe care.

**Patients' Rights** (Proposed §494.70(a)(2))

"Receive all information in a way that he or she can understand"

While we are all sensitive to the importance of providing information to patients, to mandate that the dialysis unit provide *all information*, regardless of language barriers, is, in our opinion, a situation destined for failure, even if the mechanism for providing the information is left to the dialysis unit. We would like to suggest regulatory language change such as:

"To have the dialysis facility make a clear and documented effort to assure that every patient receives all information in a way that he or she can understand."

**Patient Assessment** (Proposed §494.80)

The NPRM states "the interdisciplinary team consisting of, at a minimum, the patient (if the patient chooses) or the patient's designee..." (70 Fed. Reg. at 6203). Although we agree that it is in the best interest of the patient to take an active role in his/her care plan, not all dialysis patients choose for themselves or a designee to participate in the care planning process. We recommend the following change in regulatory language: "*the patient or his/her designee (if he or she chooses)...*"

We also recommend that a nurse practitioner or physician assistant working under the supervision of a nephrologist be able to complete the physician portion of the assessment.

*Frequency of assessment for new patients (Proposed §494.80 (b))*

This Condition needs to clearly differentiate between "first dialysis treatment" and "first dialysis treatment in an outpatient facility." Also, 20 calendar days may be unrealistic. Since elsewhere in this document CMS accepts once a month as the minimum number of times for a physician to round on patients and since it is possible that the physician would only visit an outlying rural unit once a month, then less than 30 calendar days does not make sense. In addition, patients starting dialysis are frequently unstable and require hospitalization. To make every effort to include the patient in their own assessment and care planning, on some occasions initial assessment and plan might exceed 30 days.

We would like to recommend that CMS consider that an initial comprehensive assessment be conducted within 30 calendar days after the first chronic outpatient dialysis treatment at the facility unless there is documented medical justification why this could not occur.

*Patient reassessment (Proposed §494.80 (d)(2))*

You have solicited comment regarding the implementation of a second assessment performed on new patients at the interval of three months. The intent of this section appears to be to allow a patient to stabilize so that a revision may be made in the patient's plan of care. Depending upon the acuity of the patient's condition on admission, three months might not be sufficient time for the patient to stabilize on maintenance dialysis. We would like to suggest that the second assessment of the new patient be performed at a six-month interval following admission to the facility in order to assure that an effective plan of care might be formulated.

*Patient Reassessment (Proposed §494.80 (d)(2)(i-iv))* The definition for "unstable" is vague. We are uncomfortable with terms like "extended" or "frequent" or "marked" or "significant." If the expectation is that the facility will define these, then perhaps the regulations need to so state. We would like to suggest that CMS consider that each facility must have a written definition of "unstable patient," approved by the Medical Director and using community guidelines.

**Plan of Care (Proposed §494.90)**

*Development of the Plan of Care (Proposed §494.90(a))*

You have solicited comment on the possible use of and appropriate minimum threshold for values for the adequacy of dialysis. The NKF-K/DOQI adequacy levels for Kt/V and URR are reasonable and achievable for the majority of dialysis patients. However, regulatory language should allow for flexibility in the individualized care of patients, while providing structure for the whole. The critical role that patients play in outcomes is not addressed in the regulations and we urge that it clearly be stated that documentation/justification of the failure to comply with the treatment regimen be allowed as reason for the failure to meet criteria within the plan of care.

*Development of the Plan of Care, Rehabilitation (Proposed §494.90(a)(6))*

Rehabilitation is recognized as an important aspect of quality patient care. The role of the dialysis facility in the actual provision of rehabilitative-specific care beyond education, support and encouragement is limited.

The NPRM states "the interdisciplinary team must provide the necessary care and services for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of the pediatric patient..."

While this would be ideal, limitations are acknowledged in the preamble, stating that the facility will not be held accountable for rehabilitation outcomes that are beyond the facility's control.

We suggest the wording be changed in the final regulations to the following, "*the interdisciplinary team must assist the patient in achieving the level of productive activity he/she desires by providing encouragement, educational materials, social worker support and referrals to community services.*"

*Implementation of the Plan of Care (Proposed §494.90(b)(3))*

Since it is already identified in section 494.80 (b) (2) that a follow up assessment must occur within 3 months, we believe this standard is redundant and unnecessary and we recommend deletion.

*Implementation of Patient Plan of Care (Proposed §494.90(b)(4))*

The CDC believes that the quality of patient care and the level of patient satisfaction are both improved by regular physician-patient visits. However, the proposed rule would hold dialysis facilities responsible for the activities of providers, i.e. physicians, over whom the dialysis facility has no control. We recommend the elimination of the requirement that the dialysis facility is responsible for the physician seeing the patient in the dialysis facility.

*Implementation of Patient Plan of Care (Proposed §494.90(c))*

CDC questions the benefit of duplicating transplant referral tracking already required of transplant centers. There is value in documenting in the patient record that patient's transplant status as determined by a transplant center. Transplant centers are required to notify the dialysis facility of a patient's transplant status following referral through their own Conditions of Participation. 70 Fed. Reg. at 6161 (§482.94(c)). When a patient's status changes, the transplant center should contact the dialysis facility so that it can update the patient's records. We recommend the regulatory language be changed to reflect that the patient care team maintain a list of patients on the active transplant waiting list, as provided by the transplant center.

**Care at Home (Proposed §494.100)**

*Care at Home, Support Services (Proposed §494.100 (c))*

Mandating visits to the home of patients on home hemodialysis and home peritoneal dialysis should be treated differently. Home visits to patients receiving home peritoneal dialysis should be required only when medically indicated. In the absence of a need for water treatment there is not the medical necessity for home visits for peritoneal dialysis patients as there is for home hemodialysis patients. The regulation proposes to retain the existing requirements regarding periodic surveillance of the patient's home adaptation. Routine visits to the home of patients on Continuous Ambulatory Peritoneal Dialysis (CAPD) are unnecessary as there is no equipment needed and exchanges can be done in any clean area. Visits should be as needed, e.g. frequent infections.

Routine visits for Continuous Cycling Peritoneal Dialysis (CCPD) home patients should also be done as needed since there is no water treatment required and machine disinfection and repairs to equipment are typically provided by the manufacturers' personnel. Visits should be required on the same basis as CAPD patients, only as needed for frequent infections. We recommend the language be changed to read: *"....conduct periodic monitoring of the patient's home adaptation, including home visits to the home for home hemodialysis patients and visits to home peritoneal dialysis patients if medically necessary..."*

**Personnel Qualifications (Proposed §494.140)**

*Social Worker (Proposed §494.140(d))*

We would like to propose that the definition of a qualified social worker be an individual who "Holds a master's degree in social work from a school of social work accredited by the Council on Social Work Education." We suggest deletion of section (2) regarding "meeting the requirements for social work practice in the state in which he or she is employed." Some states have been reticent to define the qualifications that would cause a social worker to meet their definition of "qualified." This has resulted in inconsistency in state surveys. Since there is a national definition of "Social Worker" as established by the Council on Social Work Education, and since CMS has determined that definition to adequately describe a professional who can provide social services in the ESRD community, we recommend deletion of the state involvement in defining social work qualifications.

*Patient Care Dialysis Technicians (Proposed §494.140(e)(3))*

The requirement that patient care technicians receive three months experience "under the direct supervision of a registered nurse" following the facility's training program needs clarification. Typically an RN is responsible for the oversight and training of all new patient care staff, but may have assistance from a preceptor who shares the same role as the new trainee. It is unrealistic to require that an RN be the only experienced personnel directly involved in the training of patient care technicians for a three-month period. We recommend revising the language to remove the word "direct" and state "This experience must be under the supervision of a registered nurse".

**Medical Records (Proposed §494.170)**

You have proposed to eliminate the requirement that facilities have written policies and procedures for record keeping. In light of the substantial requirements for written policies and procedures under the HIPAA Privacy Rule, this proposal seems short-sighted. Perhaps the inclusion of other records-related federal and state regulations "by reference" would be appropriate for the regulatory language.

*Retention and Preservation (Proposed §494.170(c)(1) and (2))*

Under 45 CFR §164.530(j), *Standards for Privacy of Individually Identifiable Health Information*, federal regulations require that "a covered entity retain documentation for six years from the date of creation or the date when it was last in effect, whichever is later." Therefore your proposal for record retention of a five-year period would seem to be in conflict with existing federal regulation and should probably be changed to six years.

**Overall comment:**

It is imperative that CMS surveyors are instructed to list a deficiency only once in the report for corrective action. We have seen one type of deficiency listed several times in a surveyor's report adding pages to make the survey look like there were several deficiencies when actually there was only one. For example, a deficiency for not testing chloramines in a timely manner could



fall under several domains of the survey. Instead of listing the deficiency under the most appropriate section, surveyors have listed the **same deficiency under 10 – 12 sections of the survey.**

**Implementation of the new Conditions for Coverage: Interpretive Guidelines**

While the Conditions for Coverage are an important framework for the survey and certification of dialysis programs, it is the interpretation by the state surveyors that will ultimately affect dialysis providers. In this regard, the CDC recommends that a panel of dialysis providers – Nephrologists, nurses, technicians and administrators, be convened to assist in the development of the interpretive guidelines used by the state surveyors. Since the state surveyors are not, in most cases, dialysis trained, the interpretive guidelines provide them with guidance to review the care of dialysis patients and the environment within a dialysis facility. This panel can provide valuable knowledge so that the surveyors will be able to better understand the specifics in providing care to dialysis patients.

The CDC appreciates the opportunity to comment on the proposed regulations. We would be pleased to meet with you to discuss our comments before the final regulations are promulgated. I can be reached at (323) 259-4771.

A handwritten signature in black ink that reads "Peter W. Crooks, M.D." The signature is written in a cursive, flowing style.

Peter Crooks, M.D.  
President  
California Dialysis Council

# Holy Name Hospital

Member  
NewYork-Presbyterian Healthcare System  
Affiliate: Columbia University College of Physicians & Surgeons

## REGIONAL DIALYSIS CENTER

718 Teaneck Road  
Teaneck, New Jersey 07666

May 2, 2005

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
File Code: CMS-3818-P  
PO Box 8012  
Baltimore, MD 21244-8012

Dear Dr. McClellan:

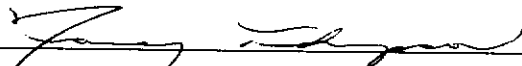
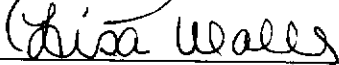

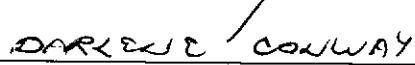
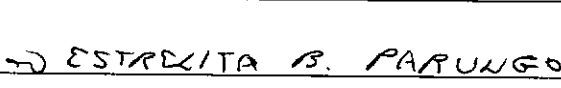


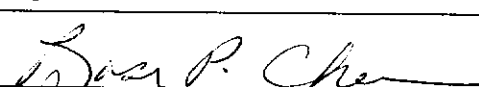
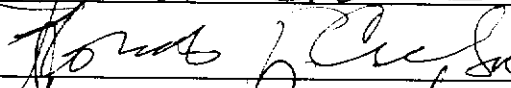

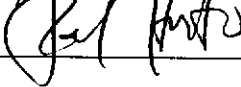
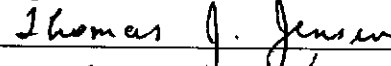
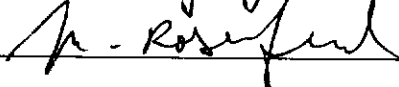
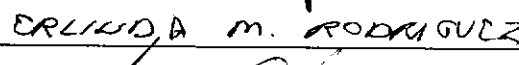
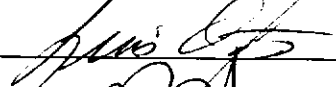
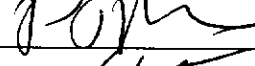
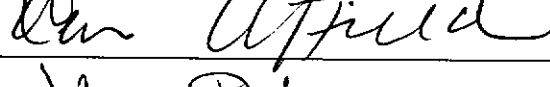

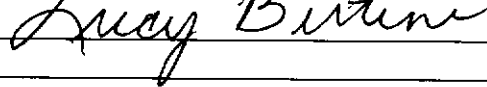
We are writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically, we wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. We appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications for us as dialysis patients.

As dialysis patients, not only are we dealing with dialysis therapy, a complicated and sophisticated procedure, but also many of us are living with high blood pressure, diabetes, heart problems and multiple consequences of kidney failure. We often take multiple medications and frequently experience problems with medication-related adverse events. For instance, a common medication regimen for many of us is three to four tablets of Phoslo three times a day for managing phosphate levels, Norvasc twice daily for high blood pressure, insulin injections three to four times daily for blood sugar, digoxin for heart problems, two to three tablets of Tums as needed for heart burn, Protonix daily for stomach problems, Aranesp for anemia, Venofer for iron loss, Hecitorol for high parathyroid hormone (PTH) level, and more.

We believe that pharmacists must be included as part of the dialysis facility multidisciplinary staff because we need a pharmacist to help us manage multiple drug therapies. A pharmacist is well trained and very knowledgeable in medications; he understands drug-drug interactions, recognizes drug duplication, identifies potential drug adverse side effects, and monitors the safety and security of drugs given to us during dialysis.

We believe among all healthcare providers, the pharmacist is best qualified to review medications and will have the most positive impact for many of us that are experiencing one of the most complicated disease conditions. We appreciate your time and consideration.

We are patients at The Holy Name Hospital's Regional Dialysis Center:

	Name (please print)	Signature
1	NANCY THOMPSON	
2	LISA WALLS	
3	FRED F AFSHAR	
4	Darlene Conway	
5	Estrelita B. Parungo	
6	C. SCHLES	
7	THALAKAVIL ROBERTSON	
8	ROSA P CHEN	
9	LORENDO P. CRUZ JR	
10	BARBARA PERRY-CLARK	
11	PAUL HIPOLITO	
12	THOMAS J. JENSEN	
13	MIKE ROSENCELO	
14	ERLINDA M. RODRIGUEZ	
15	Luis Ortiz	
16	Prasanna Nair	
17	DEVON BYFIELD	
18	IDA DIXON	
19	LUCY BERTINI	

	Name (please print)	Signature
20.	JOSEPH BEVIS JR	Joseph Bevis Jr
21.	RALPH SANDMEYER	Ralph Sandmeyer
22.	BERBERTA MOOD	Berberta Mood
23.	Salvatore Landry	SALVATORE LANDRY
24.	Adil Abdelmageed	<del>Adil Abdelmageed</del>
25.	JOHN EZZO	John Ezzo
26.	Juan Arango	Juan Arango
27.	Luis Rosario	Luis Rosario
28.	VITO A PERRULLI	Vito A. Perrulli
29.	JOSEPH SOFIA	Joseph Sofia
30.	Gloria Rotolo	Gloria Rotolo
31.	Eden DALANOUY	Eden Dalanouy
32.	Carole Davidowski	Carole Davidowski
33.	Lyndsey Langenstein	Lyndsey Langenstein
34.	S. HURST	<del>S. Hurst</del>
35.	HAROLD WARE	Harold Ware
36.	Milagros	MILAGROS
37.	Luis Villaverde	Luis Villaverde
38.	LUIS MUNNIGH	Luis Munnigh
39.	ADELINE DiPIAZZA	Adeline DiPiazza
40.	ERNEST WILLIAMS	Ernest Williams
41.	JESUS MARTINEZ	Jesus Martinez

	Name (please print)	Signature
42.	SALVATORE FRUSTIERI	Salvatore Frustieri
43.	CARMELA PINO	Carmela Pino
44.	WILLIS R. BARNES	Willis R. Barnes
45.	Kathy Mey	Kathy Meyers
46.	Kurt Bertram	Kurt Bertram
47.	KATERINA MILKO	Katerina Milko
48.	Dominick Castelluccio	Dominick Castelluccio
49.	Willard Aldrich	Willard Aldrich
50.	CHRISTIAN W. FELZER	Christian W. Felzer
51.	EDITH SUAREZ	Edith Suarez
52.	Eddie Chespo	Eddie Chespo
53.	Jamaine Hamlin	Jamaine Hamlin
54.	Linda Hall	Linda Hall
55.	Jorge Norris	Jorge Norris
56.	Danie GRATHAM	Danie Gratham
57.		
58.		
59.		
60.		
61.		
62.		
63.		

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James E. Hafner, MSW, LCSW  
6242 Glenfield Drive  
Fairway, KS 66205

May 1, 2005

Centers for Medicare & Medicaid Services  
Dept. of Health & Human Services  
Attention: CMS-3835-P  
PO Box 8013  
Baltimore, MD 21244-8013

Re: CMS-3835-P

Response to Preamble-

I am writing in regard to the proposed Conditions of Coverage for dialysis. It is good that CMS focus on outcomes and my focus will be on the aspects pertaining to social work and professional practice. In 1905 Dr. Richard Cabot, a senior physician at Massachusetts General Hospital hired the first social worker to provide social work services in an outpatient clinic. Medical social work then recognized and advocated that there should be within the health setting someone assigned to represent the patient's point of view and to work out with the physician an adaptation of the medical treatment in light of the patient's social condition. Over the years the displacement of appropriate hospital social work has brought about much of the fragmentation and issues pertaining to quality of care and cost containment that has permeated the health care arena. Today hospitals use Six Sigma methods and other Continuous Quality Initiatives to address efficiency and quality of practice concerns that had been an integral aspect of hospital social work.. In focusing on outcomes, risks develop as to process and the infringement upon staffing and corporate emphasis on cost containment only, thus not comprehensively serving the patient and the health care industry.

Similarly ESRD patients require comprehensive psychosocial interventions at various stages throughout the course of their illness due to the multiple losses and psychosocial risks associated with their diagnosis and treatment. In the Preamble CMS has shown some depth of understanding of these issues and concerns that face the ESRD patient and the quality of care that can not only bring about good adaptation to their disease process but also create the environment that allows for positive adaptation to their illness and health challenges. These same concerns need to appear in the regulations.

494.80(a) Patient assessment should be done by a "qualified social worker" so there will be no ambiguity of the social work role. There should also be an evaluation of the functioning and well being scales as measured by the SF-36 or other standardized survey that measures a physical component and mental component summary scores. This would allow for the further screening for depression if above scores were low. Evaluation



of psychosocial needs should be inclusive of the following but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, unresolved grief issues, concern about mortality & morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of (income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet & fluid), social role disturbance (familial, social, vocational), dependency issues, diminished quality of life, relationship changes, psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, locus of control, level of assertiveness to negotiate the health care system. Such elaboration will foster consistency in the assessment and measurement of the patient's capacities.

494.80(b) An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment. Recommend combining an initial team assessment and care plan as they work together. A care plan should address areas for intervention as identified in the assessment. 30 days allows for full team participation and adequate assessment of patient needs as well as time for patient to become somewhat confronted with his life changing health demands.

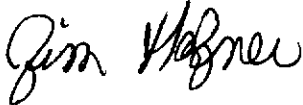
494.140 Recommend that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. It is important to delineate personnel responsibilities in some way with these new conditions of coverage to ensure that there is uniformity of services to patients throughout every dialysis unit in the country. It is just as important to outline each team member's responsibilities as it is the medical director's, as is currently proposed. Currently many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully with the patient's team and care so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis clinics and corporations do not assign social workers inappropriate tasks and responsibilities. Hospital social work has been demeaned in the same way and quality and comprehensiveness has suffered over the years.

494.140 (d) Change to Social Worker. The facility must have a qualified social worker who (1) has completed a course of study with specialization in clinical practice, and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; (2) meets the licensing requirements for social work practice in the State in which they practice; and (3) is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to

facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education, helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and encouragement regarding rehabilitation and negotiating the health care system; providing staff in-service regarding psychosocial issues; advocating on behalf of patients in the clinic and community at large.

Clinical social work training is essential for offering counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. The ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. To meet these needs it is essential that a qualified master's degree social worker trained to function autonomously is essential to ensure high standard of care and rehabilitation be provided. The Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill and competency in performance. The masters-prepared social worker can provide cost effective interventions such as assessment, education, broad range of therapy and can monitor the outcomes of these interventions to ensure their effectiveness and lessen morbidity and mortality due to depression and other psychosocial symptoms.

Respectfully submitted,



Jim Hafner, MSW, LCSW  
Dialysis Social Worker  
6242 Glenfield Drive  
Fairway, KS 66205  
913-789-9416

# ESRD

*NETWORK OF NEW ENGLAND, INC.*

## END STAGE RENAL DISEASE

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30 Hazel Terrace • Woodbridge, CT 06525 • Phone: 203-387-9332 • Fax: 203-389-9902 • E-Mail: [Info@nw1.esrd.net](mailto:Info@nw1.esrd.net)

April 29, 2005

ATTN: Teresa Casey  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
CMS-3818-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

### **RE: Conditions of Coverage for ESRD Facilities Proposed Rule (CMS-3818-P)**

Dear CMS Representative,

The ESRD Network of New England Board of Directors wish to commend CMS for the comprehensive background information on the history of the ESRD Medicare program and the organized, thoughtful discussion of the current standards, guidelines, and future proposed conditions of coverage for Medicare provider certification. We support the emphasis to use evidence-based guidelines, objective accountability, and facility-based data driven quality assessment program.

The Board has three major topics of concern, which are:

- Codifying specific measures contained in evidence-based practice guidelines as the framework of the development and monitoring of the patient's care plan is too prescriptive and rigid. The technology and science of clinical care for dialysis patients is changing at a rapid pace. New clinical measurements and target levels will emerge as more evidence unfolds. Specific target levels and treatment measures should not be detailed in the conditions of coverage. References to acceptable standards and guidelines of practice, and the consensus of the medical community, should be stated in the conditions in a similar fashion used for CDC & AAMI guidelines.
- Dialysis in Nursing Homes. We have become aware of the diverse dialysis treatment arrangements used by skilled nursing facilities (SNF) in various parts of this country. Such arrangements involve dialysis being conducted in the patient's room within the SNF, grouping patients in a treatment room within the SNF, using one hemodialysis machine for several patients within the SNF, hiring Durable Medical Equipment suppliers (DMEs) to provide the supplies/equipment and staff. These complex treatment arrangements have safety, legal, and coordination of care issues that need to be documented and researched. We recommend that CMS not address this topic in the Conditions of Coverage until more objective information is available. It is our understanding that a special project within the Network community is being supported by CMS to investigate this matter and propose recommendations.

- **Sunset Provision for Condition of Coverage.** We would recommend that these regulations contain a provision for CMS to review and update these conditions at least every five years. The state of the art regarding medical practice, modality options, and safety management change rapidly. There is a collective responsibility for oversight criteria to be evaluated on a regular basis.

#### Specific Remarks on Proposed Recommendations:

- **Subpart A General Provisions**

##### 494.10 Definitions:

The definitions for self-dialysis and home dialysis are appropriate, however, reference to the training requirements in 494.100(a) should not apply to self-dialysis since many patients perform some level of self-dialysis in the facility setting. A clear definition(s) should be established for dialysis in a skilled nursing home

- **Subpart B – Patient Safety**

##### 494.40(c)(2): Condition/Water Quality

Chlorine/chloramines testing should be done prior to each patient treatment shift. This is clear language. Adding “or every four hours” is too rigid and can be disruptive to the work schedule in the facility.

##### 494.60(c)(2): Condition - Physical Environment

Having language related to temperature level to be comfortable for the majority is too detailed and subjective to be contained in the conditions of coverage. This subject can be addressed within the provider, via a local satisfaction survey.

##### 494.60(d)(3): Emergency Equipment

The proposed language states the use of a defibrillator as part of the equipment on the emergency cart. We recommend the generic term defibrillator includes an Automated External Defibrillator (AED).

##### 494.70(a)(5): Condition - Patient Rights

We support the addition of the language to inform patient of advance directives. We recommend advance directives be included in the patient assessment plan.

##### 494.80(b)(1): Condition – Patient Assessment

The proposed language states, “the initial comprehensive assessment must be conducted within 20 calendar days after the first dialysis treatment”. We recommend the additional language be added to “after the first outpatient dialysis treatment in an ESRD provider”.

##### 494.80(a)(13): Refers to Vocational and Physical Rehabilitation Status & Potential

It will be possible to evaluate current functional status. However, evaluating potential rehabilitation status within the first 20 days may be extremely different given the mental and physical limitations of the uremic patients.

##### 494.90(a)(6): Rehabilitation Status

Concerns by providers were expressed about the extent of effort involved to do provider necessary rehabilitation/vocational services. This has the potential to be an unfunded mandate.

#### 494.90(b)(4)

CMS is holding the dialysis facility responsible for the behavior of the physician by stating, "must ensure" patient is seen monthly as evidence in progress note in medical record. The provider cannot control the behavior of the physician. In addition, the physician could fulfill this requirement by seeing patients in his/her office and never see the patient in the dialysis facility, which is not good coordination of patient care.

#### 494.90(c)

Transplant referral tracking is important data needed for the integrated management of clinical care. We are concerned that dialysis staff will be held accountable, even if there is less than acceptable feedback from the transplant program. This additional documentation of effort to communicate, and the status information, is an added unfunded requirement for staff already overextended with documentation requirements.

#### 494.100(a)(3): Condition – Care at Home

This regulation infers that the provider must "review and complete self monitoring data" at least every 2 months. We recommend that rigid requirements of all clinical indicators must be submitted as a compliance and accountability requirements could reduce the number of patients participating in home dialysis treatments. Suggest language "reasonable efforts will be made by treatment team to review self monitoring data".

#### 949.110: Condition – Quality Assessment and Performance Improvement (QAPI)

The Board is supportive of the concept of a provider-based internal quality monitoring and assessment program. Again, as stated earlier, there is merit in not listing the clinical measurement set. These areas of care may change, or not be relevant, as technology and pharmaceutical agents improve. The domains of care can be referenced to "determined by the secretary, based on evidence and current consensus of appropriate practice". We offer a word of caution when holding the facility accountable for their performance. The facility can only address management issues that are actionable and within their control. Patient choice and lack of follow-up within other treatment settings will influence process and outcome results.

#### • Subpart D – Administration

##### 494.140(a)(3): Charge Nurse

The responsibilities of clinical management of the dialysis services will be the responsibility of the charge nurse. We believe this level of responsibility should require the position to be held by a registered nurse.

##### 494.140(a)(4)(e): Patient Care Dialysis Technician

The training language in the proposed new standard for patient care technicians is not clear. The purposed language states, "complete at least 3 months experience, following a training program...under direct supervision of a registered nurse". This language would suggest that it would be a minimum of 6 months before the technician could perform his/her tasks without direct supervision. We feel 6 months would be excessive and a labor-intensive arrangement.

##### 494.140(c)(3): Dietitian

The proposed language for minimum experience states, "professional work experience". We feel the words "clinical work experience" would avoid the problem of having someone in the food service industry, with no direct clinical work, applying for this position.

494.150: Condition - Responsibilities of Medical Director

We recommend additional language to empower the Medical Director in conjunction, with the governing body, in the policies to address the substandard care of attending physicians. Additional language for Medical Directors to have major role in the appointment process of selecting individuals (MD, PA, NP) to have admitting privileges to the facility.

494.160: Condition – Relationship with the Network

Proposed language state, “in fulfilling the terms of the Network’s current state of work”. We recommend the language be consistent and recommend the statement used in 494.110 that states, “each facility must participate in ESRD Network activities and pursue Network goals”.

494.180(a)(4): Condition – Governance

As part of the educational activities/training for professional staff, it would be important to add knowledge of data analysis for quality assessment.

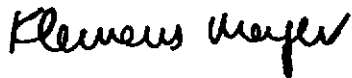
494.180(f)

Facility discharge procedures should include language that patients cannot be discharged due to non-conformance with prescribed frequency of dialysis treatment.

We acknowledge the complexity of developing comprehensive objective conditions of coverage for the safe delivery of dialysis services for patients with chronic kidney disease. We hope our comments and suggestions assist you in your work.

Sincerely,

Board of Directors of the Network of New England



Klemens Meyer, MD  
Chairman

52

# Renal Care Group

April 29, 2005

Mark McClellan, MD  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3818-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

Re: **CMS-3818-P**: Conditions for Coverage for End Stage Renal Disease  
Facilities (COC)

Dear Administrator McClellan:

Renal Care Group is dedicated to improving the quality of life and to providing optimal dialytic care for patients with chronic renal disease. Renal Care Group is committed to the philosophy that optimal dialytic care is attained through the application of continual quality improvement processes, staff education, patient/family education, and state of the art technology. We seek and have demonstrated superior patient outcomes and have documented improving patient outcomes in multiple areas of dialytic care.

We also wish to highlight the consistent and sustained improvements in several areas where dialysis providers have been able to develop action plans such as those outlined in the annual ESRD Clinical Performance measures reports.

As a company we support the overall shift in the goals of the proposed COC with the exception of the two major issues listed below. For example, since we provide patient-centered, outcome-oriented quality patient care we do not object to many of the proposed conditions. Specifically, we support the elimination of the process-oriented standards, and agree that process oriented standards do not necessarily produce quality patient outcomes or lead to this improvement.

While we commend the Center for Medicare and Medicaid Services (CMS) for a comprehensive revision to the Conditions of Coverage (COC), and the lofty goals it aims for, we have serious reservations and concerns about the expansion of the requirements and aspects of accountability in several areas which are included in the general theme of the proposed COC. At the offset, we would like to make a general comment: namely, that while the COC should reflect the appropriate requirements and optimal standards for the dialytic care of

the patient, the dialysis center is not a "health center" nor a hospital outpatient unit and cannot be the site for "disease management" of the patient on dialysis. Thus, dialysis facilities cannot be required to be responsible or accountable for two of the broad areas addressed by the COC, namely the transplantation workup [494.80 (1)(10)] and follow-up [4394.90 (a)(5)], and for a rehabilitation effort [494.80 (1)(13) & 494.50 (a)(6)] beyond providing the patient with a list of available resources and any written information CMS chooses to make available to patients and beneficiaries. These proposals highlighted in the proposed COC represent "unfunded mandates" which cannot be provided by the current staffing composition of dialysis facilities, which is predominantly technicians with limited nursing "manpower". As the United States Renal Data System (USRDS) clearly shows, a large proportion of patients on dialysis have multiple major co-morbidities, and the average age of incident patients is greater than 63 years old. Thus, achieving the lofty goals outlined in the proposed COC with respect to transplantation workup and for the detailed rehabilitative effort is a difficult, if not impossible task and bound to fail with current staffing which is shaped by CMS reimbursement policies. If dialysis providers are to be required to assume additional responsibilities for the health care needs of medically complex patients, it is imperative that Medicare's dialysis reimbursement policies be appropriately and sufficiently adjusted to allow dialysis providers to modify staffing appropriately.

Regarding the specific proposed rules that would revise the requirements that end stage renal disease (ESRD) dialysis facilities must meet to be certified under the detailed and specific Medicare program, Renal Care Group would like to submit the following comments.

#### Definitions (Proposed 494.10)

The proposed definition for Home dialysis includes a requirement that the patient or caregiver has "*completed the course of training required*". While this is reasonable in general, the inclusion of skilled nursing facilities in the definition of home dialysis and the training of staff in a nursing home facility will impose an unrealistic burden on dialysis facilities and we are opposed to the inclusion of skilled nursing facility in the definition of "home therapies". Training the staff of the nursing home facility to be dialysis caregivers is impractical. Traditionally nursing homes have a large turnover of staff which would place an unfair responsibility on dialysis facilities to keep a trained dialysis nurse on duty for all shifts. The dialysis community in general and Renal Care Group in particular does not wish to incur liability for errors due to inadequate staffing of nursing homes or inadequate training and cannot impose those requirements on the nursing home administration. We propose that CMS include the guidelines for dialysis in the nursing home as part of the requirements for COC for nursing homes, not dialysis facilities.

#### Infection Control 494.30(b)(1)

We support the incorporation of the current Centers for Disease Control and Prevention infection control guidelines. As a Company we have utilized CDC



guidelines as models for our policies. However, the proposed COC requires that *"the facility must designate a registered nurse or safety officer who maintains current infection control information, and reports to the facility's CEO or administrator and QI committee. The nurse must maintain current infection control information including the CDC guidelines for the proper techniques in the use of vials and ampoules containing medications."* The dialysis nurses administering medications, assessing patients, and monitoring care during treatment would be heavily burdened to take on another responsibility. The facility manager or their designee is a registered nurse and would be the logical choice for the "Safety Officer". In addition, we ask that the designated safety officer may serve this purpose for more than one facility.

We would also like to address how the CDC guidelines will be interpreted. The CDC guideline includes the following statements "For existing units in which a separate room is not possible, HBsAg-positive patients should be separated from HBV-susceptible patients in an area removed from the mainstream of activity and should undergo dialysis on dedicated machines. If a machine that has been used on an HBsAg-positive patient is needed for an HBV-susceptible patient, internal pathways of the machine can be disinfected using conventional protocols and external surfaces cleaned using soap and water or a detergent germicide." We would like to stress that many existing facilities do not have a separate room for Hepatitis B isolation but are following the CDC guidelines as listed above regarding an area separated from the mainstream and disinfecting the machine appropriately after the treatment. This has not resulted in a spread of the Hepatitis B virus. We would like to request the surveyors to take note of the above paragraph of the CDC guidelines.

#### Water purity 494.40

The proposed regulations state *"If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (c)(2)(i) of this section the facility must—(a) Immediately terminate dialysis treatment to protect patients from exposure to chlorine/chloramine"*. While we wholeheartedly agree with the premise that patients should not be exposed to any substances above the limit set by AAMI, however, the regulations do not provide leeway for facilities that have water holding tanks. A suggested provisional statement might be, "In the event of a chlorine breakthrough post carbon tank, the holding tank should be tested. If the water in the holding tank is less than 0.1 mg/L for total chlorine, the RO must be turned off but the product water in the holding tank may be used to finish treatments in process. Appropriate measures to address the water issues should be taken after the patient's current treatments are terminated."

#### Proposed 494.60(3) Emergency equipment and plans

The proposed regulations stipulate that *"Emergency equipment, including, but not limited to oxygen, airways, defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available"*. Supplying every facility with a "defibrillator" will be expensive.

Separate funding by CMS must be allocated for this purchase. In addition, the definition of "defibrillator" should be clarified. Use of a "defibrillator" requires a person to be Advanced Cardiac Life Support (ACLS) certified. However, the use of an "automatic external defibrillator" (AED) requires the person to have completed Basic Life Support (BLS) with AED. These distinctions require a clarification in the proposed regulations. If the provision for each facility to have a defibrillator or AED is incorporated, small rural facilities should also be included in the (funded) requirement as some of the rural facilities are not readily accessible to the local emergency response team.

Regarding emergency drugs, the spectrum of drugs should be "limited"; we strongly believe that the purpose of outpatient resuscitation is basic life support (BLS) with rapid entry into the emergency medical system (EMS), and transport to the nearest hospital, and not to provide advanced cardiac life support (ACLS) in the dialysis facility.

CMS should also propose regulations, similar to those available for other health care facilities, for a technology "pass through" that would allow dialysis facilities to serve patients with newer technologies, such as AED as well as equipment to monitor the volume or "dry weight" assessment or access blood flow that have been found to improve patient outcomes on dialysis.

#### Proposed 494.60(e) Fire Safety

The proposed rule suggests that *"The dialysis facility must meet applicable provisions of the 2000 edition of Life Safety Code of the National Fire Protection Association"*. This proposal could be expensive if the existing facility does not meet the code. We propose application of this requirement prospectively for new facilities to be built after the effective date of approval of the COC. We acknowledge that the rules allow for the facility to qualify for a waiver. However, applying for a waiver is a paperwork burden that could be avoided by applying the rule prospectively.

Proposed 494.60(2)(i) states the facility must *"maintain a temperature within the facility that is comfortable for the majority of its patients"*. This statement regarding the temperature of the facility is vague and subjective. The proposed regs should state a reasonable range of temperatures.

#### Proposed 494.70 Patients' Rights

The proposed regulations state that *"the patient has a right to be informed of their rights and responsibilities...and contains a list of 16 rights"*. Renal Care Group already provides patients with information about their rights and responsibilities. Currently we use the Network, American Association of Kidney Patients, and State required rights and responsibilities. This training or information sharing should not have to be repeated with the CMS list of rights and responsibilities. Since the Network and/or State required rights are comprehensive and balanced we see no need to change. Of note, the list of 16 rights is not specific about responsibilities of the patients, and we feel that both rights and responsibilities should be emphasized.

The wording that the patient has a right to "*receive all information in a way that he or she can understand*" (494.70(a)(2)) establishes an impossible mission. While we make every effort in our patient education material to make the language and content easily understood by most patients we suggest that the wording should be changed to "the dialysis facility must make reasonable efforts to provide information to patients in a way that he or she can understand."

#### 494.70(c) Posting of rights

*The new proposal includes a statement that the "dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network telephone complaint numbers, where it can be easily seen and read by patients."* This procedure is in place within Renal Care Group. However, we propose that in addition CMS adopt the algorithm currently in development by the CMS funded project, "Decreasing Patient Provider Conflict" as a method for facilities to use for dealing with patients who may present a danger to themselves and/or to other patients and in making good faith efforts to deal with disruptive behavior. Also, the COC needs to balance provider duties with patient responsibilities and specifically address the patient who is disruptive or threatening to other patients and or staff.

#### 494.80 (b) Frequency of assessment for new patients

*The proposed regulation state "An initial comprehensive assessment must be conducted within 20 calendar days after the first dialysis treatment".* A 20-day period to complete an assessment will be extremely difficult to meet as it often takes several visits to build rapport with patients to gather more personal information and many social workers and dietitians cover more than just one dialysis unit and are not in each facility constantly. Because the new regs also suggest an additional assessment at the 3 month mark, we would suggest the initial assessment be in two parts with part 1 being completed within 30 days and part 2 which would build on part 1 be completed within 3 months. In addition, the regs do not address the frequent occurrence of hospitalization in new patients undergoing dialysis. The facility social worker or dietitian may not actually meet the new patient in person until the patient returns from the hospital which may be after the initial 20 calendar days. We suggest wording such as, "An initial comprehensive assessment must be conducted by the 13<sup>th</sup> continuous outpatient treatment or 30 calendar days after the first outpatient treatment at that facility, which ever occurs later."

In addition "*the first dialysis treatment*" needs to be defined. The first dialysis treatment may occur in the hospital instead of the dialysis facility. Wording should include "First treatment in the outpatient dialysis facility". Using the number of sequential outpatient treatments instead of number of days would be a fair compromise on this proposal.

Proposed 494.80 Comprehensive patient assessment

CMS asked for comments on the participation of a pharmacist in the comprehensive assessment and care plan participation. Monitoring for efficient use of medications should be the responsibility of the attending physician. The dialysis facility is not funded to employ a pharmacist to monitor or participate in assessment or care planning or drug administration. Also, recall that other proposed regulations designate a "safety officer" who may monitor the appropriate (package insert information) use of the few medications used in the dialysis unit. We reiterate therefore that the involvement of a pharmacist is not warranted, and if required, should be paid for separately by specific CMS reimbursement guidelines.

494.80(a)(10) Suitability for transplantation referral, including basis for referral or nonreferral

CMS proposes that *"the patient's comprehensive assessment must include, but is not limited to, the following: Evaluation of suitability for transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon."* Many transplant centers do not have established standard criteria for acceptance but prefer to evaluate the patient individually. The wording should be changed to allow for the Nephrologist' referral of the patient to the transplant center and evaluation of the patient for transplant to be determined by the transplant center. Referral and follow up of transplant referral should be incumbent on the patient's attending Nephrologist and/or his office, not the dialysis unit personnel which has neither the expertise or time to perform such complex decisions.

494.80(d) Patient reassessment

The new proposed COC's state, *"a comprehensive reassessment of each patient and a revision of the plan of care must be conducted,—(2) at least monthly for unstable patients including, but not limited to, patients with (iv) poor nutritional status, with unmanaged anemia and inadequate dialysis"*. The definition of the word "unstable" is not defined or clear in the context of the ESRD patient with multiple co-morbidities. As written it means that a monthly comprehensive assessment will have to be documented if the patient has an albumin < 3.5, Hct < 33% or URR < 65%. These conditions may apply to 50-60% of patients in a facility and we do not believe a full comprehensive assessment is necessary in most such cases. For example, poor nutritional status defined by albumin < 3.5g/dl could apply to greater than 40% of ESRD patients and it can be long term.

Further, the regs should clarify if a patient is unstable if the URR AND the Hct are low or if one of the two indicators is low the patient is deemed "unstable". Renal Care Group recommends that "unstable" is defined as an acute condition (requiring hospitalization) and needs to be defined as such with the conditions associated with the hospitalization addressed by the facility staff and Nephrologist after the patient returns from the hospital. Renal Care Group has defined and we recommend to CMS that the definition of "unstable" is a patient

who has any of the following: (a) hospitalization resulting in significant changes in the patient's medical status, medication regimen, diet, psychosocial or functional status, (b) new substantial change in condition that is a recurrent, serious complication while undergoing dialysis (e.g., severe hypotension, seizures, allergic reactions, etc.), (c) judged unstable by the team or (d) per patient request. Under such definitions, the care plan should address the steps taken to correct the current abnormal lab value such as inadequate dialysis but should not have to include a full comprehensive assessment with every such lab value. An example that should be addressed is the large size dialysis patient with a low URR who uses an optimal dialyzer, an optimal dialysate flow, and optimal blood flow but the patient refuses to stay on treatment longer than prescribed for adequate dialysis therapy. In this situation the care plan would require the same redundant monthly note which we believe is unnecessarily burdensome. Another situation that should be considered is the patient with a catheter with poor blood flow and all possible vascular sites for an internal access have been eliminated. Again, the monthly comprehensive assessment would be repetitive under the proposed COC. To reiterate, the monthly reassessment of an unstable patient should be a focused re-assessment of the unstable aspect of care using the definition above rather than a comprehensive reassessment of chronic conditions.

Proposed 494.80(b)(2) requires "*a comprehensive reassessment within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care...*" If a patient transfers from one dialysis facility to another but has been stable on dialysis for many years, the requirement for the 3 month reassessment upon admission to the new facility seems excessive. If the assessment is required upon admission to the new facility and the patient has been stable in the prior facility then the reassessment should be repeated annually.

#### Proposed 494.90(a)(5) Transplantation status

The proposed COC's state that "*the interdisciplinary team must develop plans for pursuing transplantation*". Renal Care Group firmly believes that transplantation is the optimal therapy for patients with ESRD, and that all patients should be aware of this modality. With this stated, we also want to state that neither the information on transplantation beyond providing the patient with written materials, prepared by CMS nor the "accountability" for transplant referral can be expected from the staff of the dialysis unit. The accountability for transplant referral should be limited to the patient's Nephrologist, and the transplant referral center. The dialysis center staff has neither the responsibility, nor the time to be actively involved in this process. Dialysis unit staff have responded to the challenge of improving safety, increasing dose of dialysis, and more recently to the Fistula First initiative. These are issues that can be addressed within the four walls of a dialysis unit. But transplant referral or accountability for transplant information is not such an issue. Nephrologists are, and should remain, the primary discussant of the treatment options available to

patients, and should be the primary facilitators between the patient and the transplant referral centers.

Proposed 494.90(a) (6) Rehabilitation status

*"The interdisciplinary team must provide the necessary care and services for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of pediatric patients."* The proposal is an unrealistic expectation under today's reimbursement methodology, staffing pattern in a dialysis facility and in light of the co-morbidity of patients. Further, there is no funding for this comprehensive requirement. We propose that the wording should be "the interdisciplinary team must assist the patient in achieving the level of productive activity he/she desires by providing educational materials and referrals to community services where available."

Proposed 494.90(b) Implementation of patient care plan

As stated the proposal includes *"Implementation of the plan of care must begin within 10 calendar days after completion of the patient assessments specified in 494.80 of this part"*. This requirement does not take into account the patient who may be admitted to the dialysis facility but hospitalized within the first month. We propose to use the number of sequential dialysis treatment instead. We also feel 10 days is not long enough and should be expanded to 15 days. Therefore we suggest that the wording be changed to *"Implementation of the plan of care must begin within 15 calendar days or by the 6<sup>th</sup> continuous outpatient dialysis treatment after completion of the comprehensive assessment whichever is later"*. As stated above in our comments for section 494.80(b) (page 5 of this letter) the comprehensive assessment completion timeline should be extended to 30 days or 13<sup>th</sup> continuous outpatient dialysis treatment.

Proposed 494.90(b)(4) Direct physician/patient interaction

The new proposed regulations state, *"The dialysis facility must ensure that all dialysis patients are seen by a physician providing the ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically, while the hemodialysis patient is receiving in-facility dialysis."* While we agree with the intent of the proposed regulation, these rules place the accountability to police the physician practice on the dialysis facilities by using the wording "the facility must ensure". The language should be changed to reflect that the responsibility for physician actions falls on the attending physician for ensuring the medical progress note is included in the patient's medical record and on CMS through the revised G-codes for physicians. We would also like to see a requirement that the attending physician is required to see the ESRD patient while the patient is receiving in-center dialysis at least quarterly, not *"periodically"*. Patient focus groups have indicated that patients would feel more involved in decisions about their care with more contact from the attending physician.

Proposed 494.90(c) Transplantation referral tracking

As stated in the proposed regs, *"The interdisciplinary team must track the results of each kidney transplant center referral and must monitor the status of any facility patients who are on the transplant wait list"*. We strongly disagree with this requirement. CMS needs to require transplant centers to develop and be accountable for their own activities in terms of following up on referrals from physicians and if necessary visiting dialysis facilities to inform patients about transplant options. Adding the above standard to dialysis facilities would be dual requirement and redundant. It has been reported to Renal Care Group that some transplant centers do not keep the dialysis clinic informed of patient transplant status and this proposed requirement would place an unrealistic expectation on the dialysis facility to monitor the progress of the transplant workup. The responsibility should be delegated to the transplant center to communicate with the patient, attending Nephrologist and dialysis center on the status of the transplant workup rather than placing the burden on the dialysis center.

494.90(d) Standard Patient Education and training

Proposed wording includes, *"The patient care plan must include as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, quality of life, rehabilitation and transplantation"*. The wording should clarify "as applicable" and be more flexible to allow for situations when the family members are not available or are unwilling to participate in the patient's care, and for patients with limited cognitive function. We reiterate our specific objections related to the requirement for rehabilitation and transplantation.

494.100(b) Home dialysis monitoring

The proposed regulations require the self-monitoring data and other information from self-care patients is reviewed at least every 2 months. While we believe that this is reasonable and good, we point out that with the distance, cost, and inconvenience of travel, many stable patients do not wish to visit the dialysis facility every two months, instead visiting once a quarter. Therefore, the new regulation could be problematic for dialysis facilities. Another consideration is long distances from the facility that a patient has to travel. For example, Renal Care Group serves patients in the Aleutian Islands off Alaska who are not willing to travel to the dialysis facility every two months unless there is a problem. While we provide the opportunity for patients to visit monthly, not all patients have the financial capability to do so. The suggestions would be to change the time frame to quarterly or every three months or make the expectation of every two months be applicable to 80% of patients to allow for some exceptions. .

Request for Comments on Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities

CMS requests comment on the inclusion of a skilled nursing facility or nursing facility in the definition of "home". We do not feel the nursing facility or skilled nursing facilities have a stable provider base to provide safe and

consistent treatments to a dialysis patient in the nursing facility premises. The appropriate location for dialysis treatments is within the dialysis facility. We also refer you to our comments regarding training of skilled nursing facility (SNF) personnel.

Proposed 494.110(a)(2)(vii) QAPI Program Scope

CMS is proposing the dialysis facility develop a quality improvement program that *"must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes..."* Renal Care Group wholly supports this requirement. Our current quality management program is much more comprehensive than the suggestions listed in the proposed regs.

CMS is requesting the comments on the standardization of one patient satisfaction questionnaire to measure patient satisfaction within all dialysis companies. Renal Care Group does not support the development of a CMS imposed common instrument. Currently we have a comprehensive tool that is utilized within our Company. We benchmark year to year to trend improvements. We also modify questions over time to address and improve issues specific to Renal Care Group. We wish to continue use of our current tool.

Proposed 494.120(d) Physician contact for special purpose renal dialysis facilities

This standard requires that *"The facility must contact the patient's physician, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care."* The proposal that the special purpose renal dialysis facility contact the patient's attending physician prior to initiating dialysis in emergency situations is ideal but unrealistic. In the event of hurricanes or other natural disasters the telephone lines are often disabled. There should be a provision for another physician to be able to provide emergency care in these extenuating circumstances.

Proposed 494.140(b) Nursing services

The proposed regulation states that the nurse manager must *"be a full time employee of the facility"*. As CMS clearly knows there is a shortage of qualified registered nurse managers. Requiring a full time manager for every facility, especially small rural facilities, is not a good use of this scarce resource. Some small facilities share a nurse manager between two facilities with experienced, certified licensed practical nurses monitoring care. We recommend elimination of this requirement.

Proposed 494.140(d)(1) Social Worker

The new regulations states, *"The facility must have a social worker who holds a master's degree in social work from a school of social work...."* It appears that the "grandfather" clause for "bachelors prepared" social workers has been eliminated. We propose that individuals who hold a Bachelor's Degree in Social



Work could assist those with a Masters in Social Work with concrete resource tasks but not have their own specific caseload. The Council on Nephrology Social Work has a job description for bachelor prepared social workers that could be referenced. CMS's interest in having Social Workers do more intensive counseling services, long term behavioral and adaptation therapy, and grieving therapy is not realistic with current staffing ratios without additional funding and provision for privacy during counseling, which is almost impossible in all dialysis units. We propose CMS review the job description for the "bachelors prepared" social worker for inclusion in the definitions.

Proposed 494.140(3)(3) Patient care dialysis technicians

The wording of proposed 494.140(e)(3) should be revised. It states that patient care dialysis technicians must "have completed at least 3 months experience, *following* a training program that is approved". The word "following" may be interpreted two ways. It may be interpreted as meaning "after" or "utilizing". For example a surveyor might expect the person must have 3 months experience AFTER they completed the training program prior to being allowed to provide direct patient care without supervision. Another interpretation would be the patient care technician must have 3 months experience, UTILIZING an approved training program. We strongly recommend the latter interpretation, since a total of 3 months training is adequate for most technicians.

Proposed 494.150 Condition: Responsibilities of the Medical Director

In this proposed condition it states that the responsibility of the medical director includes, *"Quality assessment and performance improvement program and all policies and procedures relative to patient care and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers"*. We support the recommendations that the ESRD conditions for coverage specify the responsibilities of the Medical Director in general and in situations when there is a quality problem related to an ESRD facility attending physician. We also believe that the medical director should have the authority to conduct or initiate peer review and to address performance problems through directed education and for more serious situations, the medical director's responsibility is to report a non-performing attending physician to an authoritative body such as the ESRD Network or the State Medical Board for action that violates facility or CMS guidelines.

Proposed 494.170(b)(1) Medical Records

CMS requested comments regarding the necessity of revising the current phrasing regarding completion of patient records and centralization of clinical information. The current wording that medical records and those of discharged patients are completed promptly is sufficient.

Proposed 494.170((d) Transfer of Medical Records

We agree that the transfer of medical information to a receiving facility is necessary and in the best interest of the patient. However, we recommend that the statement "medical record" be defined more clearly. We propose that such

records include (and for the COC to specify the minimum of) the Care Plan, three most recent dialysis flow sheets, medication list, laboratory report, comprehensive assessment by members of the multidisciplinary team, and physician orders (if applicable).

Proposed 494.180(2) Governance

The new proposed regulation includes the following statement, "A *registered nurse is present in the facility at all times that patients are being treated*". This country is experiencing the worst nursing shortage crisis in history. Requiring a registered nurse to be present for all treatments will set up many facilities for failure and could result in closure of some facilities. Licensed Practical Nurses (LPN) with the appropriate experience, training, and certification are more than capable of managing the day to day operations of a chronic outpatient dialysis facility. This requirement should be modified to allow for these experienced, well trained and certified LPN's to function in the absence of a registered nurse. The qualifications for a medical director are much more lenient by allowing a physician who has completed a "board-approved" training program in nephrology or even an internist with 3 years experience to practice as the medical director. This flexibility should be expanded to include licensed practical nurses. By not allowing licensed practical nurses to function in the absence of a registered nurse can cause undue hardship in rural areas where there are severe registered nurse shortages.

Proposed 494.180(b)(5) Adequate number of qualified and trained staff.

The proposed regs necessitate "*There is an approved written training program specific to dialysis technicians. And .... under the direct supervision of a registered nurse*". We agree with this recommendation. RCG has an extensive training program for new dialysis technicians that far exceeds the requirements listed in the proposed. We also have a training program for water treatment technicians that is mandatory for all personnel and completely support the inclusion of this requirement in the new regulations. However, we feel the definition of the term "direct supervision of a registered nurse" needs to be clarified. We believe a registered nurse should oversee the training program but not be present at this trainee's side constantly for 3 months.

Proposed 494.180(b)(1) Standard: Adequate number of qualified and trained staff.

CMS solicited comments regarding acuity- based ratios. Acuity based ratios will foster confusion and a tendency to "up-coding" in the dialysis facility because it will take time to determine and document the acuity of each patient. This will also create additional paperwork burden. Dialysis facility staff have enough duties taking care of the dialysis patients without having to maintain more paperwork documents. If acuity-based ratios are adopted, then payment for dialysis treatments should also be adjusted for acuity in order for providers to be able to accommodate acuity-based staffing needs.

Proposed 494.180(f)(iv) Discharge and transfer policies and procedures

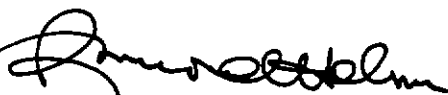
The proposed regulations includes a statement that the dialysis facility, "Notifies the State survey agency and the ESRD Network that services the area (where the facility is located) of the involuntary transfer or discharge." The proposal is unreasonable. It adds another unnecessary paperwork burden to the dialysis facilities. Currently the ESRD Networks are notified. It is not necessary to notify the State survey agency in addition to the ESRD Network. We propose to limit notification to one or the other agency but not both.

494.180(h) Furnishing data and information for ESRD program administration

CMS is requiring that data and information "Be submitted electronically in the format specified by the Secretary". The VISION software that CMS will be providing to small and medium size companies should be made available to all providers free of charge, not just small to medium size companies and independent facilities. If it is mandatory then the software should be made available to all dialysis providers free of charge. CMS should also provide funding for travel related to training for any trainee attending the training classes. There should be financial relief for the abstracting and key-entry of CPM data and ISP annually. Any software implementation should never require duplicate data entry into multiple systems.

In summary, Renal Care Group dialysis facilities provide patient-centered, outcome oriented quality patient care. We support the overall shift from an emphasis from a process-oriented to outcome-oriented approach. However, many of the proposed requirements are not dialysis specific, nor should be dialysis facilities or dialysis staff responsibilities. We would like to meet with CMS to discuss the proposed COC and answer any additional questions you may have regarding our comments.

Sincerely,



Raymond Hakim, MD, PhD  
Senior Executive Vice President, Clinical Affairs  
& Chief Medical Officer  
Renal Care Group



Linda Dickenson, RN, BSN, CNN, CPHQ  
Special Projects Director  
Renal Care Group

53

Paukert Dialysis Inc.  
Napa Valley Community Dialysis Center, Inc  
1100 Trancas St. #267  
Napa, CA 94558  
(707) 224-6533

Department of Health and Human Services  
Attention: CMS-3818-P  
PO Box 8012  
Baltimore, MD 21244-8012

To Whom It May Concern:

Dr. Thomas Paukert and myself, Sheryle Paukert are the co-owners of Paukert Dialysis Inc. We have managed Napa Valley Community Dialysis Center, Inc. since 1986 and have owned it since 1993. We pride ourselves on giving our patients the best possible care. We have used the flexibility inherent in a small independent clinic to provide early implementation of innovations in dialysis to the benefit of our patients. We believe that the changes we have identified in the proposed conditions will present such a regulatory and administrative burden that we will be unable to continue in business as an Independent Dialysis Facility.

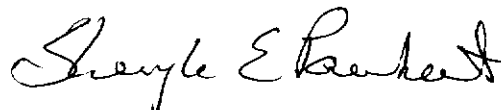
Small clinics are under intense financial pressures. CMS' own figures from cost reports show that for Medicare patients independent facilities are being paid less than the full cost for providing care. We cannot take on additional responsibilities and costs whether they be for administration, supplies, professional salaries or other items and remain financially viable. Historically small clinics have led the way in the implementation of advances in dialysis. It is not in the best interest of the patients to drive the small independent clinics out of business with unfunded mandates and additional administrative burdens.

We have attached our comments on the proposed conditions. We hope revisions are made which will allow us to continue our independent status.

Sincerely,



Thomas T. Paukert M.D.  
Medical Director and Co-owner



Sheryle E. Paukert R.N., M.S.N., N.P.  
Administrator and Co-owner

NAPA VALLEY COMMUNITY DIALYSIS CENTER, INC. RESPONSE TO THE  
PROPOSED RULE : CONDITIONS OF COVERAGE FOR END  
STAGE RENAL DISEASE FACILITIES

494.30 Infection Control

We are cognizant of the need to reduce cross contamination between patients in the dialysis unit. We maintain supplies in a central clean area but there are occasions when staff must have immediate access to Personal Protective Equipment such as gloves. It is often difficult to predict when a patient might suddenly start bleeding, especially during the access clotting process at the end of dialysis. The staff must react immediately to stop the bleeding. It is uneconomic to have gloves of every size at the patient's chair, but gloves do need to be readily available in the case of unexpected patient bleeding for protection of the staff from blood borne infectious agents. This can be most easily achieved by having a small supply on the staff's person in a pocket. Staff is willing to take the time to grab gloves from a pocket, but is not likely to run to a central location to get gloves. Staff safety must take precedence over potential cross contamination.

Dedicated staff and machines in the case of Hepatitis B seroconversion is prohibitive in a small hemodialysis center. The requirement will force small units to deny access to their facilities to all Hepatitis B positive patients.

494.40 Water Quality

Required chlorine/ chloramines testing should be required before each patient shift. The issue is about the quality of water patients come in contact with during treatment and every four hour testing is excessive.

494.60 Physical Environment

The existing 405.2140 (d) (3) addresses emergency situations, but does not clarify what is in a "fully equipped emergency tray". This language is retained in the new conditions and the "fully equipped emergency tray" is still left undefined. This can lead to differing interpretations by DHS examiners especially in the area of emergency medications. We would suggest limiting emergency medications to those usually used to combat anyphalaxis. More extensive emergency medications are appropriate to an inpatient setting where nurses are qualified as Advanced Cardiac Life Support (ACLS) members of a response team. Such a team is not available in an outpatient dialysis clinic.

## Patients Rights

### 494.80 Patient Assessment

Twenty (20) days to complete a multidisciplinary assessment is an unreasonably short period. Patients are present on different days and different shifts and all team members must complete the patient assessment. Thirty days as is the present regulation is already difficult to achieve.

Many hemodialysis centers have more than one transplant center that is evaluating ESRD patients. Having to document suitability for transplant based on each transplant center's criteria is an overwhelming burden for the dialysis center.

It is unreasonable to document all of the patient's abilities, preferences, goals and expectations in the proposed assessment in the proposed timeframe of 20 days. Many patients are not in sufficiently recovered health to be able to adequately respond to questions in the first few weeks of dialysis.

Measuring delivered dose of dialysis (Kt/v) every month is burdensome for the patients, as most must collect a 24 hour urine sample, and for staff as it requires additional staff time and effort to do the calculations. Measured delivered dose of dialysis would be more reasonable every other month. URR could be evaluated in the alternate months.

It is not in alignment with the chronic nature of ESRD to include "poor nutritional status" under "unstable patients" which, therefore, must have a care plan review each month. Poor nutritional status is many times a chronic problem that is multifactorial over which ESRD centers have minimal influence.

### 494.90 Patient Plan of Care

It is beyond the scope of practice of a Dialysis Center to set a timetable to achieve "measurable and expected outcomes" on chronic patients, particularly those whom are ESRD for over one year. Many chronic problems are extremely complex and as such frequently defy even the professional's ability to predict how long they will take to solve.

494.90 (c) Tracking each ESRD patient's transplant status is the responsibility of the transplant center, not the hemodialysis center. Dialysis Clinics should be expected to transmit information to the Transplant centers, but the burden for tracking the required information should rest with the Transplant center.

#### 494.90 (a) (2) Nutritional Status

Patients come to an out-patient center to receive treatment and then go home. There are not additional moneys set aside to provide meals or even oral nutritional supplements by centers. It is unreasonable to make the center's multidisciplinary team responsible to "provide the necessary care and services to achieve and sustain and effective nutritional status".

Patient Plan of Care continued

494.90 (a) (6) Rehabilitation Status

This amounts to an unfunded mandate. Current funding barely covers the ongoing responsibility to provide safe and effective dialysis treatments. This condition would expand the scope of services to include rehabilitation without providing funding for personnel to provide the rehabilitative services. Physical rehabilitation services that currently are provided by other referral agencies are usually limited in time so the patient generally only receives a start but does not achieve full rehabilitation. ESRD staff other than Social Workers are not trained in rehabilitative skills nor are knowledgeable to provide the required interventions in "physical, occupational, and recreational therapy". ESRD patients and centers already have an enormous burden with the transportation of patients to and from dialysis centers just for treatments, the addition of transportation to and from rehabilitation, support groups and other activities will overwhelm the system.

494.90 (b) Implementation of the Patient Plan of Care

Facilities are already strained in bringing together the multidisciplinary team once a month. A requirement to have the multidisciplinary team complete the Patient Plan of Care within ten (10) days after the Patient Assessment is an undue burden upon the facility. Care plans could be finalized in the first multi disciplinary meeting held following the completion of all the assessments.

494.90 (b)(4) The facility cannot ensure that the patient will be seen by the physician every month. Patients are often non-compliant about keeping appointments with the physician, even if the dialysis clinic takes an active role in setting up the appointments. The existing G codes provide ample incentive for the physician to see the patients as often as is medically necessary. It is an undue burden to place on the dialysis clinic to track and ensure patient/physician visits.

The belief that it is necessary to periodically see the patient in the clinic on dialysis to be able to address the patient clinical concerns and needs in the treatment environment is flawed. Patient outcomes, CPMs, and face to face visits in the physician office are adequate for complete patient care. There is no evidence that physician visits in the clinic are in any way more effective than visits in other venues. To insist on periodic dialysis clinic rounds for all patients may place an undue burden on physicians who cover geographically remote clinics where patients typically come in to the physician office for monthly visits. Many patients prefer the privacy of the doctor's office setting over the dialysis clinic openness.

494.90 (d) Patient Education and Training (In-Center Hemodialysis)

The expansion of this condition to include education for all the life changes associated with the initiation of dialysis is an unfunded mandate which will require the dialysis units to hire additional personnel skilled in the provision of this education and training. The items included in mandated training and education, such as employment opportunities, rehabilitation activities, transplant requirements and the many other issues alluded to, are beyond the scope of expertise of most dialysis technicians and nurses.

D: Condition: Care at Home

494.100 (c)(1)(VI) The requirement that dialysis facilities must deliver supplies and equipment to the home patient will give an unfair advantage to Method II suppliers, especially for a clinic which serves a large geographic area.

494.100 Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities  
This proposal oversteps the bounds of responsibility for the dialysis clinic. The training and monitoring of the Home Care patient is the responsibility of the dialysis clinic, but the supervision of employees of a separately licensed facility should not be the responsibility of the dialysis clinic. This proposal will serve to discourage clinics from pursuing expansion of services into Skilled Nursing Facilities.

QAPI

494.110 (a) (2) Patient Satisfaction in the QAPI program

Patient Satisfaction Survey as a formal instrument should only be required annually. The proposed QAPI elements are mostly measured monthly, but a formalized patient Satisfaction Survey would be burdensome to both the clinic patients and staff if administered on a monthly basis. An annual questionnaire combined with a monthly tracking of patient formalized grievances brought to the care team should serve to give monthly QAPI data.

Although a common instrument seems like a good idea, regional expectations and cultural differences may serve to skew the results and not accurately reflect patient true satisfaction with their dialysis situation



## Personnel Qualifications

### 494.140 (e) (3) Dialysis Technicians

One stated premise of the new conditions is to have outcome-based criteria. It would seem that setting arbitrary time requirements for staff training is counter-productive to ensuring competency. The training of a Hemodialysis Technician (HDT) should be initiated by an experienced HDT. HDTs generally have extensive knowledge of and experience with dialysis machines and many of the technical aspects of the dialysis clinic. An experienced HDT can more competently train the new technician for the daily tasks of Hemodialysis than can most Registered Nurses. In addition, the requirement for direct supervision of the technician trainee by a Registered Nurse is unduly burdensome to the facility, especially in view of the present Registered Nurse shortage and concomitant high cost. States such as California have set standards for HDT training that define appropriate training requirements. We have found that these requirements can be met by a combination of training by experienced HDTs and Registered Nurses. Technicians do work under the general supervision of a Registered Nurse in the dialysis clinic. Registered Nurses should be in charge of the training of the HDT in psychosocial skills and in the didactic training of the HDT.

### 494.140 (6) Other Personnel Issues

Dialysis facilities are not the prescribing agent, therefore the pharmacist does not have a role within the dialysis facility. We favor maintaining the collaborative role we already enjoy with the patient's community pharmacist.

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**214/366-6290**

April 29, 2005

Centers for Medicare & Medicaid Services  
 Department of Health and Human Services  
 Attention: CMS-3818-P  
 PO Box 8012  
 Baltimore, MD 21244-8012

I wish to respond to the proposed Conditions of Coverage for End Stage Renal Disease Facilities. I have worked for 21 years as a nephrology social worker in hemodialysis, peritoneal dialysis and transplant. I have previously served as National Chair of the Council of Nephrology Social Workers.

The change suggested to 494.140 d below will be very important to helping patients achieve optimal rehabilitation outcomes and functioning that helps them to live life to their fullest potential.

I am also attaching three articles that I wrote in support of interventions provided by the qualified social worker. The first article is from *Dialysis and Transplantation*. "The Role of the Nephrology Social Worker in Optimizing Treatment Outcomes for End-Stage Renal Disease (ESRD) Patients." 27 (10). The second article is "A Model for Patient Participation in Quality of Life Measurement to Improve Patient Rehabilitation Outcomes" published in *Nephrology News and Issues*, 13 (1). "Nephrology Social Work Interventions and the Effect of Caseload Size on Patient Satisfaction and Rehabilitation Interventions", *Journal of Nephrology Social Work*, 1998, Vol. 18.

<p><b>494.80</b>  <b>Condition</b>                      Patient                      assessment                      (a) Standard:                      Assessment                      criteria.</p>	<p><b>Change:</b> The language of "social worker" in the first sentence to "<b>qualified social worker</b>"</p> <p><b>Rationale:</b> This is very important as many people call themselves social workers who are not MSW's. This will help to clarify the social work role.</p> <p><b>Add:</b> (a1) "...and functioning and well-being using a standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component summary (MCS) score and all domains of functioning and well-being measured by that survey. If the MCS or mental health domain score is low, assess for major depression using a validated depression survey or referring the patient to further mental health evaluation."</p>
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	<p><b>Rationale:</b> The preamble to the <i>Conditions for Coverage</i> discussed the importance of measuring functioning and well-being—but stated that there was “no consensus” about which measure to use. In fact, the literature clearly supports the value of the PCS and MCS scores to independently predict morbidity and mortality among tens of thousands of ESRD patients—and these scores can be obtained from any of the tools currently in use to measure functioning and well-being. The composite scores (PCS and MCS) have been proven to be as predictive of hospitalization and death as serum albumin or Kt/V. Scores can be improved through qualified social work interventions.</p> <p><b>References:</b> DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer &amp; Williams, 2003; Lowrie, Curtin, LePain &amp; Schatell, 2003; Mapes et al., 2004</p> <p><b>Comment:</b> I support the language of a2, a3, a4, a5, a6</p> <p><b>Change:</b> (a7) to “Evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality &amp; morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of [income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid], social role disturbance [familial, social, vocational], dependency issues, diminished quality of life, relationship changes; psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers).”</p> <p><b>Rationale:</b> Much like the elaboration of a1, a4, a8, a9, elaborating what “psychosocial issues” entails will ensure national consistency of the exact psychosocial issues that must be assessed for each patient. There is clear literature that identifies these psychosocial issues throughout this response.</p> <p><b>References:</b> ESRD Network 14, ESRD Professional Standards, Social Service Practice Recommendations (<a href="http://www.esrdnetwork.org/professional_standards.htm">http://www.esrdnetwork.org/professional_standards.htm</a>)</p>
<p><b>494.70</b>  <b>Condition</b>            Patients' Rights            (a) Standard:            Patients' rights</p>	<p><b>Add:</b> (new 17) “Have access to a qualified social worker and dietitian as needed”</p> <p><b>Rationale:</b> Social workers and dietitians often have large caseloads, cover multiple clinics and/or work part-time, and patients often do not know how to contact them when needed.</p>

	<p><b>References:</b> Bogatz, Colasanto, Sweeney, 2005; Forum of ESRD Networks, 2003; Merighi &amp; Ehlebracht, 2004a ; Callahan, 1998</p>
	<p><b>Add:</b> (new 26) "Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of his illness, developmental issues affected by his illness, and any behavior that negatively affects his health or standing in the facility."</p> <p><b>Rationale:</b> Patients are faced with numerous adjustment issues due to ESRD and its treatment regimes. Master's level social workers are trained to intervene within areas of need that are essential for optimal patient functioning and adjustment</p> <p><b>References:</b> McKinley &amp; Callahan, 1998; Vourlekis &amp; Rivera-Mizzoni, 1997; Callahan, 1998</p>
<p><b>§494.180</b>  <b>Condition</b>  Governance.  (b1) Standard.  Adequate  number of  qualified and  trained staff.</p>	<p><b>Add:</b> (1i) No dialysis clinic should have more than 75 patients per one full time social worker.</p> <p><b>Rationale &amp; References:</b> A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will leave ESRD care in the same situation as we have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (we would recommend CNSW's staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language about social work ratios, we strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel who have limited understanding of social work training or role to determine social work staffing).</p> <p>Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman &amp; Maceda, 1998). It is also the case that social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, &amp; Ehlebracht, 2002, 2005). In Merighi and Ehlebracht's (2004a) survey</p>

of 809 randomly sampled dialysis social workers in the United States, they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, and 47% had caseloads of more than 100 patients.

In a recent study by Bogatz, Colasanto, and Sweeney (2005), nephrology social workers reported that large caseloads hindered their ability to provide clinical interventions. Social work respondents in this study reported caseloads as high as 170 patients and 72% of had a median caseload of 125 patients. The researchers found that 68% of social workers did not have enough time to do casework or counseling, tasks mandated by the current conditions of coverage, 62% did not have enough time to do patient education, and 36% said that they spent excessive time doing clerical, insurance, and billing tasks. One participant in their study stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients are being denied access to quality social work services' (p.59).

Patient-social work ratios are critical so that social workers can effectively intervene with patients and enhance their outcomes. It is clear that social work intervention can maximize patient outcomes (doing these requires reasonable ratios):

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.
- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). A study currently being conducted by Cabness shows that social work intervention is related to lower depression.

Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social

	<p>worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses by Rubin, et al. (1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.</p>
<p><b>494.80</b> <b>Condition</b> Patient assessment (b) Standard. Frequency of assessment for new patients</p>	<p><b>Change:</b> (b1) to "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment. Initial contact by members of each profession should take place within 2 weeks of admission to facility or 6 hemodialysis treatments."</p> <p><b>Rationale:</b> Combining an initial team assessment and care plan would facilitate a care plan that address areas for intervention as identified in the assessment. Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs. Initial contact</p>
<p><b>494.80</b> <b>Condition</b> Patient assessment (d) Standard: Patient reassessment</p>	<p><b>Support:</b> (d2iii) to "significant change in psychosocial needs"</p> <p><b>Rationale:</b> A patient's needs and goals change during the course of many years with ESRD treatment. Psychosocial assessment should be ongoing and should help to focus psychosocial interventions to improve outcomes.</p> <p><b>Add:</b> (v) "Physical debilitation per patient report, staff observation, or reduced physical component summary (PCS) score on a validated measure of functioning and well-being."</p> <p><b>Rationale:</b> Low PCS scores predict higher morbidity and mortality in research among ESRD patients.</p> <p><b>References:</b> DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer &amp; Williams, 2003; Lowrie, Curtin, LePain &amp; Schatell, 2003; Mapes et al., 2004; Callahan, 1998.</p> <p><b>Add:</b> (new vi) "Diminished emotional well-being per patient report, staff observation, or reduced mental component summary (MCS) score on a validated measure of functioning and well-being."</p> <p><b>Rationale:</b> Low MCS scores predict higher morbidity and mortality in research among ESRD patients. Low MCS scores are also linked to depression and skipping dialysis treatments.</p> <p><b>References:</b> DeOreo, 1997; Kalantar-Zadeh, Kopple, Block, Humphreys, 2001; Knight et al. 2003; Kroenke, Spitzer &amp; Williams,</p>

	<p>2003; Lowrie, Curtin, LePain &amp; Schatell, 2003; Mapes et al., 2004; Callahan, 1998.</p> <p><b>Add:</b> (new vii) "Depression per patient report, staff observation or validated depression screening survey"</p> <p><b>Rationale:</b> Multiple studies report a high prevalence of untreated depression in dialysis patients; depression is an independent predictor of death.</p> <p><b>References:</b> Andreucci et al., 2004.; Kimmel, 1993; Kimmel, 1998; Kutner et al., 2000.; Wuerth, Finklestein &amp; Finklestein, 2005</p> <p><b>Add:</b> (new viii) "Loss of or threatened loss of employment per patient report"</p> <p><b>Rationale:</b> Poor physical and mental health functioning have been linked to increased hospitalizations and death. Loss of employment is linked to depression, social isolation, financial difficulties, and loss of employer group health plan coverage. Identifying low functioning patients early and targeting interventions to improve their functioning should improve their physical and mental functioning and employment outcomes.</p> <p><b>References:</b> Blake, Codd, Cassidy &amp; O'Meara, 2000; Lowrie, Curtin, LePain &amp; Schatell, 2003; Mapes et al., 2004; Witten, Schatell &amp; Becker, 2004</p>
<p><b>494.90</b>  <b>Condition</b>  Patient plan of care.  (a) Standard:  Development of patient plan of care.</p>	<p><b>Add:</b> (new 3) "<i>Psychosocial status</i>. The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status."</p> <p><b>Rationale &amp; References:</b> Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof &amp; Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of the care plan.</p> <p><b>Add:</b> (new 6) Home dialysis status. All patients must be informed of <i>all</i> home dialysis options, including CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, and nocturnal home hemodialysis, and be evaluated as a home dialysis candidate. When the patient is a home dialysis candidate, the interdisciplinary team must develop plans for pursuing home dialysis. The patient's plan of care must include documentation of the</p> <p>(i) Plan for home dialysis, if the patient accepts referral for home</p>

	<p>dialysis;</p> <p>(ii) Patient's decision, if the patient is a home dialysis candidate but declines home dialysis; or</p> <p>(iii) Reason(s) for the patient's non-referral as a home dialysis candidate as documented in accordance with § 494.80(a)(9)(ii) of this part.</p> <p><b>Rationale:</b> Home therapies allow greater flexibility, patient control, fewer dietary and fluid restrictions, need for fewer medications, potential for improved dialysis adequacy, and improved likelihood of employment. CMS has stated encouragement of home dialysis as a goal. Every patient must be informed of home dialysis options, evaluated for candidacy for home dialysis, and, if not a candidate, the reason(s) why not should be reported. This allows quality assessment and improvement activities to be undertaken in the area of home dialysis.</p> <p><b>Add:</b> (renumbered 8) "Rehabilitation status. The interdisciplinary team must provide the necessary care and services to:</p> <p>(i) maximize physical and mental functioning as measured minimally by physical component summary (PCS) score and mental component summary (MCS) score on a validated measure of functioning and well-being (or an equally valid indicator of physical and mental functioning),</p> <p>(ii) help patients maintain or improve their vocational status (including paid or volunteer work) as measured by annually tracking the same employment categories on the CMS 2728 form</p> <p>(iii) help pediatric patients (under the age of 18 years) to obtain at least a high school diploma or equivalency as measured by annually tracking student status.</p> <p>(iv) Reasons for decline in rehabilitation status must be documented in the patient's medical record and interventions designed to reverse the decline."</p> <p><b>Rationale:</b> The goals of the current proposed section are vague, not measurable, and not actionable. To improve rehabilitation outcomes, facilities must meet certain standards. From the perspective of the Medical Education Institute, which administers the Life Options Rehabilitation Program, "rehabilitation" can be measured by a functioning and well-being vocational assessment. Functioning and well-being (measured minimally as PCS and MCS) predict morbidity and mortality. Annually tracking employment status through Networks using the same categories on the CMS 2728 and including this as a QAPI would improve the likelihood that rehabilitation efforts would be successful.</p>
§494.110 Condition Quality assessment and performance	<p><b>Add:</b> (2)(new iii) "Psychosocial status."</p> <p><b>Rationale &amp; References:</b> Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the</p>



<p>improvement. (a) Standard: Program scope.</p>	<p>intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including Auslander, Dobrof &amp; Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of quality improvement. (Callahan, 1998) CNSW has many resources and tools, available through the National Kidney Foundation, that can be used to track social work quality.</p> <p><b>Add:</b> (2)(new ix) "Functioning and well-being as measured by physical component summary (PCS) and mental component summary (MCS) scores (or other equally valid measure of mental and physical functioning) and vocational status using the same categories as reported on the CMS 2728 form"</p> <p><b>Rationale:</b> These scores provide a baseline and ongoing basis for QAPI activities to improve patient rehabilitation outcomes.</p>
<p><b>494.140</b> <b>Condition</b> Personnel qualifications</p>	<p><b>Comment:</b> CNSW recommends and I support that this section be renamed "Personnel qualifications and responsibilities", with the addition of specified personnel responsibilities to each team member's qualifications. If it is decided that adding "personnel responsibilities" to this section is inappropriate, we would suggest the alteration of 494.150 to be renamed "Condition: Personnel Responsibilities" and include a discussion of the responsibilities of each team member (instead of just the medical director as is currently proposed). CNSW suggests possible responsibilities for social workers in the next section, where we comment on "494.140 Condition Personnel qualifications (d) Standard: Social worker." These suggestions can be used in a new "responsibilities" section.</p> <p><b>Rationale &amp; References:</b> It is critically important to clearly delineate personnel responsibilities in some fashion in these new conditions of coverage to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. It is just as important to outline each team member's responsibilities as it is the medical director's, as is currently proposed. This is especially important regarding qualified social work responsibilities. Currently, many master's level social workers are given responsibilities and tasks that are clerical in nature and which prevent the MSW from participating fully with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage specify the responsibilities of a qualified social worker so that dialysis</p>

clinics do not assign social workers inappropriate tasks and responsibilities. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten & Johnstone, 1997). Russo (2002) found among the nephrology social workers that he surveyed 53% were responsible for making transportation arrangements for patients, and 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units). Only 20% of his respondents were able to do patient education. In the Promoting Excellence in End-of-Life Care 2002 report, End-Stage Renal Disease Workgroup Recommendations to the Field, it was recommended that dialysis units discontinue using master's level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families. Merighi and Ehlebracht (2004b; 2004c; 2005), in a survey of 809 randomly sampled dialysis social workers in the United States, found that:

- 94% of social workers did clerical tasks, and that 87% of those respondents considered these tasks to be outside the scope of their social work training.
- 61% of social workers were solely responsible for arranging patient transportation.
- 57% of social workers were responsible for making travel arrangements for patients who were transient, which required 9% of their work time.
- 26% of social workers were responsible for initial insurance verification.
- 43% of social workers tracked Medicare coordination of benefit periods.
- 44% of social workers were primarily responsible for completing patient admission paperwork.
- 18% of social workers were involved in collecting fees from patients. (Respondents noted that this could significantly diminish trust and cause damage to the therapeutic relationship).
- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time spent assessing and counseling patients.
- Only 34% of the social workers thought that they had enough time to sufficiently address patients' psychosocial needs.

This evidence clearly demonstrates that without clear definition and monitoring of responsibilities assigned to the qualified social work (as is the current case), social workers are routinely assigned tasks that are inappropriate, preventing them from doing appropriate tasks. **For all of**

	<b><i>these reasons, CNSW is strongly urging the addition of "personnel responsibilities" to the new conditions of coverage (either in this section, or the next section).</i></b>
<b>494.140</b> <b>Condition</b> <b>Personnel</b> <b>qualifications</b> <b>(d) Standard:</b> <b>Social worker.</b>	<p><b><i>Change the language of d to:</i></b> <i>Social worker.</i> The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting patients with achieving their rehabilitation goals (including: overcoming barriers ; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks.</p> <p><b><i>Rationale &amp; References:</i></b> Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make the definition congruent to that of a qualified social worker that is recommended by CNSW for the transplant conditions of coverage. CNSW supports the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree. We agree</p>

that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition.

Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared

social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above.

It is clear that social work intervention can maximize patient outcomes:

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.
- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003).

Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology

	<p>social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.</p>
<p><b>494.140</b>  <b>Condition</b>            Personnel            qualifications</p>	<p><b>Add:</b> (e) Standard: Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who- As supervised by the unit social worker, performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient treatment paperwork and verifies insurance coverage.</p> <ul style="list-style-type: none"> <li> <p><b>Rationale &amp; References:</b> I agree with the preamble that dialysis patients need essential social services including transportation, transient arrangements and billing/insurance issues. I also firmly agree with the preamble that these tasks should <u>not</u> be handled by the qualified social worker (unless the social worker has fewer than 75 patients per full time equivalent social worker), as caseloads higher than this prevent the MSW from participating fully with the interdisciplinary team so that optimal outcomes of care may be achieved. It is imperative that the conditions of coverage identify a new team member who can provide social service assistance-the preamble recommends that these clerical tasks should be done by someone other than the MSW, but does not specify who that person is. Adding this section (e) will eliminate any ambiguity surrounding this issue, and ensure adherence to this recommendation across all settings. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prevent nephrology social workers from performing the clinical tasks central to their mission (Callahan, Witten &amp; Johnstone, 1997). Russo (2002) found that all of the nephrology social workers that he surveyed felt that transportation was not an appropriate task for them, yet 53% of respondents were responsible for making transportation arrangements for patients. Russo found that 46% of the nephrology social workers in his survey were responsible for making dialysis transient arrangements (which involved copying and sending patient records to out-of-town units), yet only 20% were able to do patient education.</p> </li> </ul>

	I support a ratio of 75 patients per full-time equivalent qualified social worker. If a dialysis clinic has fewer patients per full-time equivalent social worker than less than 75:1, the social worker can address concrete social service needs of patients. However, patient ratios over 75 patients per full-time equivalent social worker require a case aide.
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Thank you for your review of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'M. Callahan', with a long horizontal flourish extending to the right.

Mary Beth Callahan, ACSW/LCSW

### **Abstract**

The relationship between psychosocial interventions and treatment effectiveness is reviewed in this article. It identifies four predominant psychosocial risk factors in the end-stage renal disease population which are predictors of morbidity and mortality. Depression, social support, albumin management, and patient perceived quality of life are reviewed with a focus on the effectiveness of psychosocial interventions that can directly impact morbidity and mortality. The effectiveness of the educational preparation of the nephrology social worker is also reviewed.

**Key words:** depression, social support, quality of life, morbidity, mortality, nephrology social work



**THE ROLE OF THE NEPHROLOGY SOCIAL WORKER  
IN OPTIMIZING TREATMENT OUTCOMES FOR END-STAGE RENAL  
DISEASE (ESRD) PATIENTS**

**POSITION:** Due to the increasingly complex biopsychosocial and cultural profile of the U.S. ESRD patient population (1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17) and due to the overwhelming evidence of the impact of biopsychosocial variables and psychosocial interventions on ESRD treatment outcomes (17,18,19,20,21,22,23,24,25,26) the National Kidney Foundation's Council of Nephrology Social Workers supports the continued requirement of a masters-prepared social worker, licensed in the state if applicable, to provide psychosocial services to ESRD patients.

The Council of Nephrology Social Workers reviewed the literature to determine if psychosocial risk factors in the ESRD patient population still indicate the need for masters-prepared social workers and adopted this position in August 1998. This paper summarizes the review of literature relating to the relationship between interventions provided by nephrology social workers and ESRD treatment outcomes, as well as, the training and effectiveness of masters preparation in working with this population.

**DESIRED ESRD PATIENT OUTCOMES AND RELATED PSYCHOSOCIAL BARRIERS**

For the ESRD patient, psychosocial outcomes focus on improving functional status, patient-perceived quality of life, patient satisfaction and rehabilitation. In turn, these outcomes impact other general outcomes such as treatment adequacy, morbidity and mortality (6, 7, 8, 27, 28). Like other chronic illnesses, ESRD treatment outcomes are affected by a patient's psychological, social and economic circumstances (7, 29). Psychosocial interventions that focus on improving patient-perceived quality of life and well-being are key in maximizing overall ESRD treatment outcomes (1, 30, 31, 32).

Outcome-driven care, such as this, must include tools for accurate outcome measurement. Quality of life instruments provide this measure for nephrology social work services in providing a "picture over time" of functional status and well-being from the patient's perspective. This is a key element in accomplishing the purpose of the Medicare ESRD program which focuses upon rehabilitation. Rehabilitation, which may or may not include employment, is defined as restoration to a previous level of functioning (33). The ability to assess the complex interrelationship of psychosocial variables that impact rehabilitation will be increasingly important in the era of managed care. The additional training of masters-prepared social workers supports this goal of the Federal ESRD program.

The industry, focused on delivering quality care while containing the growing costs of the ESRD

program, is increasingly aware that more ESRD patients are capable of working than actually do work (34, 35). The literature points to the use of outcome measurements to identify barriers to vocational rehabilitation (36, 37) and associates vocational rehabilitation with medical, psychological and social adaptation (12, 18). Research also supports the impact of psychosocial factors in the maintenance of employment among hemodialysis patients (23, 24, 25, 35, 38).

Early intervention, education and psychosocial support have a positive effect on maintaining employment as well as reducing hospitalizations to support employment (34, 39, 40, 41). In addition, patient's expectations of the medical team, especially their nephrologist and their social worker, as well as family members, significantly influence a patient's perception of their ability to work (42). This is consistent with another study of patient expectations which related that greater than 84% of patients rely on clinical social workers to assist them with coping strategies, family adjustment, the impact of dialysis on their life and continuing family activities (43). Finally, when discussing the role of the masters-prepared social worker in the ESRD setting, it is helpful to look at the quantifiable psychosocial barriers to achieving the above mentioned outcomes. Masters-prepared social workers are indicated in the ESRD setting to provide interventions that identify and ameliorate problematic circumstances that could contribute to poor patient outcomes in all areas (44).

### **THE RELATIONSHIP BETWEEN PSYCHOSOCIAL INTERVENTIONS AND ESRD TREATMENT OUTCOMES**

Four major psychosocial risk factors that impact morbidity and mortality will be discussed. The effect of timely and appropriate psychosocial intervention to improve these risk factors are enhanced by the additional educational preparation of the masters-prepared social worker. Skilled psychosocial interventions have been shown to have a positive impact on ESRD patient outcomes (4) and patient perceived quality of life (1, 45) in addition to reducing medical costs (41, 46).

#### **Depression is a predictor of morbidity and mortality**

Because cognitive depression in the ESRD population has been found to be an important predictor of mortality (7, 16, 47), treatment effectiveness (48, 49), and patient adjustment to ESRD diagnosis (50), skilled social work interventions directed at treating depression are critical to quality patient care. The provision of clinical interventions by a masters-prepared social worker is a highly cost-effective means of providing indicated mental health services to ESRD patients (20, 21, 51, 52, 53). Research indicates that a decrease in depression correlates positively to increased compliance which has a direct impact on morbidity and mortality (54,55).

Psychosocial interventions are driven by skilled biopsychosocial assessment that focuses on predictors of adaptation such as previous coping style, family system health, support system, developmental strengths, social role functioning, pre-morbid norms for well-being, mood disorders, mental status and socioeconomic supports (56).

In-depth screening of these indicators has become increasingly important as recent studies point to increasing rates of depression (25%-60%) among the ESRD population (12, 54, 57, 58). The increased risk and incidence of suicidal ideation and passive suicide through dietary and treatment non-compliance (13, 14, 15, 59, 60) make routine screening for depression an important function of the nephrology social worker. Recent studies indicate that 76% of depressed patients would

prefer to seek counseling from the nephrology social worker on their treatment team rather than pursue care from another individual (66). The nephrology social worker must possess the training to assess the differential diagnosis of depression, against conditions such as dementia and uremia whose symptoms can mimic those of depression.

Affective disturbance, cognitive impairment and memory loss (61, 62, 63) are known barriers to effective education. Because the patient's health status, needs, goals and environment continually change (39, 64) and because adequate assessment and treatment lead to improved patient outcomes (14, 65, 66), the nephrology social worker must provide ongoing assessment to maximize treatment outcomes (56) such as adaptation to chronic illness.

Patient compliance depends on understanding, patient-perceived value to health outcome, and perception of vulnerability (54). Coping with chronic illness requires several cognitive-behavioral skills that help the patient control the adverse effects of the disease by adhering to the demands of the treatment regimen (67, 68). Cognitive-behavioral interventions can increase dietary adherence, decrease depression and increase life satisfaction in ESRD patients (17, 26, 35, 37, 69, 70, 71, 72, 35) as well as increase rehabilitation potential (73).

Masters-prepared social workers are provided additional training in assessing barriers to adaptive coping and providing brief cognitive-behavioral treatment in order to enhance important variables of effective patient care. Increasingly, nephrology social workers are showing positive outcomes from cognitive-behavioral interventions with ESRD patients in the areas of patient compliance and adaptation to illness (45, 71, 72, 74, 75, 77) which decreases morbidity and mortality.

### **Social Support is a Predictor of Morbidity and Mortality**

Strong evidence exists that social support, particularly from the family, profoundly influences overall morbidity and mortality and the course of chronic illness (7, 77, 78, 79). Additionally, family stress and multiple family losses related to the illness may play an important role in mediating the outcome of ESRD treatment (2, 5, 80, 81). Research shows that ESRD often impacts marital role and marital adjustment (82) as well as changes in other relationships (83) by impacting the functioning of the family system (64).

Family psychoeducation is the most consistently effective type of intervention used in working with families who have a member with chronic illness (84). Nephrology social work interventions such as family education (50) and family therapy improve patient compliance and assist the patient and family to cope with and adapt to changes brought about by illness and hospitalizations (64, 72, 85, 86). This supports the patient in achieving improved functional status.

Group therapy also increases social support, quality of life, and physical health for patients (87). Groupwork with the chronically ill focuses on education, communication issues, health behaviors, increasing coping capacities and psychosocial adjustment (87, 88, 89, 90). Groupwork outcomes include decreased somatization and unnecessary medical visits (91) and significant reductions in mood disturbance and pain (70, 88). Groupwork can also improve the overall rehabilitation potential of young persons with ESRD (92).

The additional individual, family and groupwork training received by a masters-prepared social worker allows for the cost-effective provision of this intervention in the ESRD setting. These interventions are aimed at increasing social support, which has a direct impact on morbidity and mortality.

### **Albumin Management is a Predictor of Morbidity and Mortality**

Serum albumin is accepted as a predictor of mortality (93, 94). Many psychosocial risk factors are related to albumin management. These include:

- a) problems obtaining food or nutritional supplements
- b) inability to cook/need for personal care
- c) need for dentures
- d) assistance needed to purchase groceries
- e) decreased appetite due to depression or anxiety
- f) decreased cognitive capability to manage diet
- g) isolation

Many complex biopsychosocial factors affect the ESRD patient across a lifetime and can have a direct impact on treatment effectiveness and albumin management. These can include: changes in self-worth (9) and role functioning, multiple losses, changes in financial security, problems with sexual functioning, functional limitations, dependency (10), uncertainty of the future (11, 95), financial hardship, changes in job status, disability and discrimination in insurance and employment, aging (61, 96, 97, 98) and rural residence (99, 100, 101).

It has been shown that elders from small towns and rural communities have a higher rate of Medicare hospital discharges per 1,000 enrollees than do their counterparts in metropolitan areas (102). Some of the sociodemographic characteristics of older persons who live in small towns and rural communities place them in a disadvantaged position relative to their urban counterparts which could put them at increased risk for poor health outcomes (100). Americans living in rural communities and those from lower socioeconomic levels have less access to health care, especially preventive services (103) which makes them more vulnerable to the psychosocial risk factors of albumin management.

Socioeconomic factors such as income, wealth, education, literacy, ethnicity, culture, household composition, life histories, insurance and social supports may be potential barriers to achieving desired outcomes, such as albumin management. These risk factors have the potential to create increasing physical and emotional debilitation throughout the ESRD patient's life cycle (2, 104) and can negatively impact adherence to medical recommendations. Additionally, cognitive and mood changes, including depression and anxiety, can negatively impact adherence to albumin management and other medical recommendations and increase medical costs (53, 54, 58, 105). A patient's maladjustment to the diagnosis of ESRD often results in personal neglect, social withdrawal and non-adherence to treatment regime. These factors have a direct influence on physical outcome (106) and albumin management. Thus, these variables become important predictors of treatment effectiveness (17).

Biopsychosocial risk factors and medical complications impact the overall functioning of the ESRD patient and related treatment outcomes, such as albumin management (44, 61, 104, 107). The nephrology social worker must be skilled in assessing for these underlying influences and

their interrelatedness in predicting treatment outcomes. The nephrology social worker must also be able to design interventions with the patient, the family, the medical team and community systems at large to maximize the effectiveness of ESRD treatment. The additional training received by a masters-prepared social worker enables them to perform these complex professional tasks and ensure effective outcomes that have a direct relationship to morbidity and mortality.

#### **Patient Perceived Quality of Life is a Predictor of Morbidity and Mortality**

Quality of life can be used to predict mortality risk and hospitalization risk (27, 54, 107, 108). Quality of life is also closely associated with the assessment of functional status and well-being which have been identified as valuable indicators of the effectiveness of medical care (31, 36). In addition to physical function, quality of life tools measure specific psychosocial variables such as social functioning, emotional functioning, mental functioning, and depression. These variables correlate with physical symptom components and death risk in studies of ESRD patients. (27, 109).

Using only biologic functioning in defining treatment does not take the whole person into account. Medical treatment of any kind involves trade-offs that have different meanings to different individuals. Treatment of ESRD involves many trade-offs such as time involved for treatment and lifestyle changes required to adhere to medical recommendations. Traditional medical assessments often ignore human functioning as well as personal and social utility (110). Quality of life is gaining recognition as an important outcome measurement in the clinical evaluation process because treatment is often aimed at improving patient well-being, not simply longevity (109). It is an important step in a multistage diagnostic screening process. Quality of life measurement assists in the translation of the extent to which biologic changes create a change in patient-perceived health. Masters-prepared social workers are trained to utilize validated tools, such as the SF36 and KDQOL, to improve care. They can also develop instruments to monitor the outcomes of their directed interventions, assess the complex variables that these instruments measure (45, 74, 61, 107, 111), and continually redesign a plan of care to achieve outcome goals.

The masters-prepared social worker provides the interdisciplinary team with a biopsychosocial view of the patient's strengths and needs (112, 113) through use of patient-perceived quality of life measures and the person-in-environment model of assessment (114, 115). One recent study with hemodialysis patients showed that a social work intervention aimed at including the patient in setting rehabilitation goals increased interdisciplinary team care planning interventions to support these rehabilitation goals (45). Defining the patient's individual goals as part of the treatment plan is enhanced through quality of life measurement and is an integral component of interdisciplinary care planning (45). Because the emphasis in medical social work is on the mutual interaction of the patient and the patient's context (64), the nephrology social worker's ongoing biopsychosocial assessment provides the basis for collaborative team interventions to ameliorate psychosocial problems that have a direct impact on treatment outcome (44). The partnership between the patient and the interdisciplinary team is strengthened through patient-perceived quality of life measurement. This strengthens interdisciplinary collaboration that enhances problem solving to achieve desired outcomes (116) such as decreased morbidity and mortality.

#### **EFFECTIVENESS OF MASTERS-PREPARED SOCIAL WORK INTERVENTIONS**

Most nephrology social workers provide psychosocial services autonomously as primary providers without social work supervision or consultation. Autonomous practice in an ESRD

setting demands the highly developed and sophisticated social work intervention skills provided by a masters level curriculum. Nephrology social workers must have outcome evaluation skills and must understand the interaction among individual systems, the social system, and the medical system as each impacts patients and families. They must be able to distinguish between normal adjustment reactions and more debilitating and potentially self-destructive emotional reactions, as well as tailor interventions to the individual coping styles of the ESRD patient (4). Finally, they must be prepared to contribute to the development of clinical pathways to enhance treatment outcomes.

The masters level curriculum in social work provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. The Masters in Social Work degree (M.S.W.) is the only curriculum which offers this additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior. Undergraduate (B.S.W.) degrees, or other mental health credentials (M.A. in counseling, sociology, psychology or Ph.D. in Psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and social systems. The National Association of Social Workers Standards of Classification considers the Baccalaureate degree as a basic level of practice (117, 118). Under these same standards, the Masters in Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (119).

Masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (120) and are trained to autonomously provide diagnostic, preventive and treatment services for individuals, families and groups in the context of their life situations. (121).

These interventions assist ESRD patients in developing adaptive behaviors and perceptions necessary to cope with the changes brought about by chronic illness and hospitalization. Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (122, 123, 124). Perhaps that is why they are identified as major mental health service providers in both urban and rural areas (125).

To summarize, research has shown that psychosocial interventions can independently yield measurable outcomes. Masters prepared social workers are trained to autonomously provide these skilled interventions. Baccalaureate social workers (B.S.W.'s) are not trained to provide autonomous or independent, specialized care in any arena. Only the masters level practitioner is qualified to provide specialized services (126). Other mental health providers are not provided specialized training in the relationship between Bio-Psycho-Social-Cultural variables and multiple social systems and thus have not performed as effectively in social work jobs (122). Masters training has been shown to make a significant difference over baccalaureate preparation in job performance in the areas of individual and relationship counseling and therapy, inservice and education to a multidisciplinary team, team collaboration, care planning, assessment and crisis intervention (123) and impact on depression (12).

## **SUMMARY**

This paper has reviewed the relationship between psychosocial interventions and ESRD treatment outcomes, desired ESRD treatment outcomes and related biopsychosocial barriers to achieving those outcomes, and the training and effectiveness of the masters-prepared social worker.

ESRD patients experience multiple losses and psychosocial risks associated with their diagnosis and treatment. They require comprehensive psychosocial interventions at various stages throughout the course of their illness. The lifetime course of the ESRD patient's treatment may include multiple renal transplants, vascular access problems, life-threatening infections, amputations, severe bone disease, family dysfunction, changes in functional status, depression and issues of death and dying.

Barriers exist in the socioeconomic and biopsychosocial realms that negatively impact patient treatment outcomes such as morbidity and mortality. The identification of these barriers through a skilled biopsychosocial assessment is critical to maximizing patient outcomes. Providing skilled psychosocial interventions based on this assessment can ameliorate biopsychosocial risk factors, thus improving treatment outcomes for the ESRD patient. Patients are more likely to access these assessment and treatment services through the nephrology social worker on their treatment team than elsewhere. One recent study showed that patients ranked the services provided by the nephrology social worker in the top four of twenty-five important aspects of care (127). A 1994 study showed that ninety-one percent of the patients believed access to a nephrology social worker was important (43).

An additional 900 hours of specialized, clinical training prepares the masters level social worker to work autonomously in the ESRD setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness. Finally, the additional two years of training prepares the masters level social worker to collaborate with the interdisciplinary team in designing an individualized patient care plan that achieves positive outcomes.

As the End Stage Renal Disease program looks toward the future, it must insist on a care delivery system in which each member of the treatment team deploys refined skills that increase patient perceived quality of life, patient satisfaction, social functioning, mental functioning, physical functioning and rehabilitation in a cost-effective manner. **For these reasons, the National Kidney Foundation's Council of Nephrology Social Workers supports the continued requirement of a masters-prepared social worker, licensed in the state if applicable, to provide psychosocial services to ESRD patients.**

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### *Abstract*

#### **A Model for Patient Participation in Quality of Life Measurement to Improve Patient Rehabilitation Outcomes**

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Health-related quality of life (HRQOL) measurement is being used to assess end-stage renal disease (ESRD) patients' functional status and well-being from the patient's perspective. Research shows that HRQOL can screen for patients at high risk for death, hospitalization, treatment adherence and depression. This study investigated whether patient goal setting and interdisciplinary collaboration and support could increase HRQOL scores in ESRD patients on chronic maintenance hemodialysis. Ten in-center for-profit hemodialysis facilities participated.

Differences were found to be statistically significant in two of the SF36 categories (role physical and role emotional) following the intervention at the 95% confidence interval using a t-test statistic. This indicates that the intervention had a positive impact on patient perceptions of their health status. Eighty-seven percent indicated that there had been at least some progress made in reaching the goal .

The results of this study support the utilization of HRQOL data at the facility level to improve patient's perceptions of their health status. Further study is needed to examine the long-term impact on HRQOL and other patient outcome measures through consistent use of this intervention.

## A Model for Patient Participation in Quality of Life Measurement to Improve Patient Treatment and Rehabilitation Outcomes

Health-related quality of life (HRQOL) measurement is being used to assess functional status and well-being from the end-stage renal disease (ESRD) patient's perspective. Research shows that HRQOL data can screen for patients at high risk for death, hospitalization, treatment adherence and depression (Lowrie et al, 1998; DeOreo, 1997; Kimmel, 1995; Kimmel, 1993). This measurement can be incorporated into interdisciplinary care planning to improve interventions and outcomes; however, it has not yet been routinely interpreted and utilized at the facility level. As the ESRD industry moves toward progressive models of patient-centered care, consensus is forming that a patient's subjective assessments are more valuable than objective measures such as the Karnofsky (Kutner, 1994). The utilization of HRQOL data involves a change in day-to-day activities and mindsets of physicians, social workers, nurses, and dietitians on the renal team. In addition to a change in mindset, the relationship between HRQOL data and care delivery must be clarified for renal professionals and that clarification begins with patient-centered care (Curtin et al, 1998).

Simply stated, patient-centered care focuses on meeting the needs defined by the patient (Wakefield et al, 1994). HRQOL can be used to effectively and efficiently provide this care in three ways:

1. to monitor clinical indicators (Meyer, 1994; DeOreo, 1997);
2. to continually assess for patient change
3. to design effective care plans (Faden & LePlege, 1992).

Systematic use of patient-perceived HRQOL allows the clinician to review problems of social functioning and well-being in much the same way that laboratory reports bring attention to potential deviations in biologic functioning. Though aggregated value structures can be useful from a systems perspective to design general care guidelines, the value of HRQOL may be the ability to capture the values and personal goals for medical care of *individual* patients.

The value of patient self-report studies becomes increasingly important in a health care system that is soon to be dominated by managed care. H. David Banta, MD, formerly Assistant Director of the U.S. Office of Technology Assessment, said "caring is really the essence of health care" (Banta, 1990). Patient-perceived HRQOL enhances the clinician's focus on the human aspects of healing while the benefits of highly developed medical technology is provided (Caputi, 1982). Interventions such as the review of HRQOL data and setting related goals with the patient as well as collaborating with the interdisciplinary team in the review of these areas could add a dimension of caring and focus that may otherwise be lost in the hurriedness of the clinician's busy practice. Research shows that the relationship between patients and staff impacts both the patient's perception of support and satisfaction with care—both determinants of health care outcomes (Johnstone, 1997).

Comprehensive care for the patient is complex, particularly in the ESRD population where the goal is not merely to extend life, but to extend meaningful life for the patient as defined by the

patient's values. This includes not only improving physical functioning, but also relieving pain and suffering, easing anxiety and fear through compassionate interactions, and improving general functioning and well-being (Faden & LePlege, 1992).

### **Study Design and Patient Population**

The purpose of this study was twofold. The study aimed to assess whether HRQOL measurement and interpretation of scores could assist the renal team in designing individualized patient care plans. Secondly, the study sought to determine whether designing multidisciplinary interventions based on HRQOL scores could increase the patient's perception of well-being and quality of life. Ten in-center for-profit hemodialysis facilities participated. Control and experimental sites were equally divided between two separate geographical areas of the United States. Because the MOS Short Form 36 (SF36) was already being utilized in these dialysis centers, it was chosen as the HRQOL instrument for this study. Prior to this study, aggregate data was being collected from the SF36 surveys completed by patients, but facilities were questioning how to interpret and utilize the resulting data. In general, members of the direct care team had not yet had access to this important data.

The patients in the study were randomly selected at the control and experimental facilities. Because of difficulty in providing the chosen intervention, patients whose primary language was not English and those who were not oriented were excluded from this study. Surveys for the control group were scored and compared to the experimental group at one month and four month intervals. The experimental group was composed of five facilities that would score the randomly sampled 20 patients and follow the proposed protocol for intervention. The control group was

defined as five facilities that would not score the surveys or use the surveys for interdisciplinary collaboration and intervention.

Nephrology social workers were provided training in scoring and interpretation of the SF-36, then they administered the SF-36 surveys to the patients involved in the study. The survey was completed independently by the patients who could read. The survey was read by the nephrology social worker when the patient had literacy or vision barriers.

The intervention protocol for the study called for the nephrology social worker to lead the interdisciplinary team in an understanding of the SF-36 scores and to enlist the support of the interdisciplinary team to design interventions to increase patient rehabilitation. Social, physical, vocational, emotional, or functional rehabilitation outcomes were equally valued. The nephrology social worker explained the study to the patient and informed consent was obtained. The explanation provided to the patient related that scoring and reviewing the SF-36 survey could:

- 1) help the patient communicate with the staff by providing insight into their perceptions of their disease process and
- 2) allow the patient a chance to identify what they would like to see improve and work with the team in creating this improvement.

The focus of the intervention was on the patient setting his/her own goals and the interdisciplinary team mobilizing around those goals to provide clinical support for the patient. The interpretation of the HRQOL data by the nephrology social worker to the interdisciplinary team allowed each

health care team member to incorporate their unique clinical strengths to enhance the assessment and development of strategies to assist the patient in accomplishing their goal. This is consistent with studies that reflect that interdisciplinary team management, in partnership with the patient, enhances cooperation and problem solving to achieve desired outcomes (Chan et al, 1997).

### **Hypothesis**

The hypothesis of this study was that when four steps were completed in implementing the SF-36, patient rehabilitation outcomes would be enhanced as evidenced by their next SF-36 survey and response to the question: "How close are you now to the goal we set four months ago?" Those four steps included: 1) explaining the survey to the patient, 2) scoring the survey (which was not being done otherwise), 3) explaining the patient's results to the patient and encouraging the patient to identify a goal to achieve over the next four months, 4) sharing the SF-36 results and patient goal with the interdisciplinary team.

### **Data Analysis**

After patients had completed the SF-36, the social workers scored them using the *SF-36 Health Survey Manual and Interpretation Guide* (1993). Each of the eight categories within the SF-36 is scored separately. These categories include physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. T-tests for paired samples were used to compare continuous variables for pre- and post-group data.  $P < 0.05$  was considered to be statistically significant. Simple descriptive statistics were used to analyze patients' perceptions of reached goals.

#### **Demographics**

##### **Experimental**

The sample was made up of 59 patients. There were 39 (64.4%) females and 21 (35.6%) males in the sample. The sample was ethnically diverse with 22 (37.3%) identified as Caucasian, 18 (30.5%) African-American, 15 (25.4%) Hispanic, and 4 (6.8%) Asian. The sample was comprised mostly of older adults; only 14% were under the age of 40. Those patients 70 years of age or older made up 25% of the sample.

##### **Control**

The sample taken from the same population as the experimental group was made up of 73 patients. Of these, 35 (47.9%) were female and 38 (52.0%) were male. It was also an ethnically diverse group, consisting mostly of Caucasian and African-American patients with 37% and 31.5%, respectively. The Hispanic group was the next largest at 20.5%, followed by Asian patients at 9.6%. As in the experimental group, the largest age groups were those 41-55 years and 56-70 years. Only 17.8% were under 40 years old.

Using a chi-square statistic, it was found that the differences in the two groups were not statistically significant at the 95% confidence interval. This is important because it gives strength to the comparability of the two groups. Demographic data for experimental and control groups are compared in Table 1.

## **Results**

The research hypothesis sought to determine if there would be a meaningful difference between the pre- and post groups because of the intervention of goal setting with the patient through the use of the SF-36. Participating patients were easily able to identify an area of their functional status or well-being that they desired to improve. Some of these included: wanting to feel more energy, wanting to improve functioning of hand, wanting to decrease pain from arthritis so that walking was possible, being able to make their own bed, being able to do some household tasks again, decreasing loneliness and anxiety, being able to garden and fish again, becoming more fit for transplant, being able to look after grandchildren again, and becoming less dependent on family through improved physical functioning.

Interdisciplinary care planning with the patient's goal as the primary focal point encouraged the design of varied interventions that reflected the skills of each team member. For examples, see Table 2.

Differences were found to be statistically significant in two of the SF-36 categories at the 95% confidence interval using a t-test statistic. Both role-physical and role-emotional had a significant difference in scores between the pre- and post-groups, providing evidence that the intervention improved HRQOL scores.

To determine if the intervention (goal-setting through the use of the SF-36) was a variable that contributed to an increase in individual SF-36 results, a t-test was performed on the control group which resulted in no statistically significant difference in pre- and post-group scores. To discover the effectiveness of the intervention of clarifying and supporting a patient-defined goal, social workers asked the patients in the experimental group to rate how much progress, if any, had been made towards reaching the goal. Eighty-eight percent indicated that there had been at least some progress in reaching the goal. Specifically, 42% of respondents stated they had reached the goal and 46% stated they had made some progress in reaching the goal. Only twelve percent indicated that they had made no progress in reaching the goal. This suggests that the patient's perception of reaching the goal was an important variable in the intervention outcome though this data needs further examination.

## **Discussion and Implications for Practice**

Patient-perceived quality of life measurement allows for the patient's perceptions to be gathered in a systematic way and included as part of the nephrology social worker's ongoing biopsychosocial assessment and plan for intervention. Through this process the interdisciplinary team's understanding of the patient's feelings and attitudes toward their illness can be increased. The utilization of a HRQOL instrument, as demonstrated in this study, can include the patient as the central focus from which care planning is developed. This study suggests that interventions that increase patient participation with the HRQOL instrument can lead to enhanced quality of life and well-being. The outcome that 87% of the participants in the experimental group perceived that progress was made toward their identified goal is significant and may have secondary positive

gains not accounted for in this data analysis.

Another outcome measure that could be studied is the correlation of patient satisfaction with care and progress made toward their goal. Additional research could also determine the degree to which each variable mediated the change in HRQOL scores. The research could examine the role of: 1) team support, 2) establishment of a goal by the patient, 3) interpretation of HRQOL results to the patient and interdisciplinary team in affecting a change in the patient's perceptions. Measurement of patient perceptions and outcomes over a longer period of time could also provide valuable insight regarding the efficacy of the intervention.

HRQOL measurement will become increasingly important in the managed care paradigm. Renal care teams are currently refocusing and redesigning efforts in care delivery to fit this new

environment. Interdisciplinary team utilization of HRQOL measurement can be a practical and effective solution to improving treatment outcomes in a patient-driven care environment.

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**Table 1**  
**Demographic Data of Experimental and Control Groups**

	Frequency Experimental Group	Frequency Control Group	Percent Control Group	Percent Control Group
<b><i>Gender</i></b>				
Male	21	38	35.6	52.0
Female	38	35	64.4	47.9
<b><i>Ethnicity</i></b>				
Other	0	1	0	1.7
Asian	4	7	6.8	9.6
Black	18	23	30.5	31.5
Hispanic	15	15	25.4	20.5
White	22	27	37.3	37.0
<b><i>Age in years</i></b>				
15-25	1	0	1.7	0
26-40	7	13	11.9	17.8
41-55	18	19	30.5	26.0
56-70	18	25	30.5	34.2
70+	15	16	25.4	21.9

**Table 2**  
**Case Examples**

<i><b>Patient Goal</b></i>	<i><b>Interdisciplinary Team Interventions</b></i>	<i><b>Patient Assessment of Progress Toward Goal</b></i>
To get stronger and be able to go home from nursing home; improve physical and emotional functioning.	<ol style="list-style-type: none"> <li>1. Work closely with nursing home staff ; establish good communications.</li> <li>2. Invite nursing home staff to the dialysis center for exchange of information on patient.</li> <li>3. Encourage compliance to medications.</li> <li>4. Counseling by social worker to strengthen family relationships; schedule counseling with husband present if possible.</li> <li>5. Increase communication with daughter who will be primary caregiver when patient returns home.</li> <li>6. Encourage patient to maintain good hygiene to decrease risks of infection.</li> </ol>	Patient response to: How close are we now to the goal we set four months ago? "The goal has been reached."
To decrease pain from arthritis which keeps him from doing his daily activities; be better able to walk	<ol style="list-style-type: none"> <li>1. Referral to orthopedist for evaluation and treatment.</li> <li>2. Maintain good weight gain.</li> <li>3. Encourage appropriate exercise program to strengthen muscles and have better circulation of blood.</li> <li>4. Encourage adherence to renal diet.</li> <li>5. Affirm patient as he continues to take responsibility for his physical, emotional and mental well-being.</li> </ol>	Patient response to: How close are we now to the goal we set four months ago? "The goal has been reached."

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## **ABSTRACT**

Satisfaction with care is considered an outcome measure that may receive greater focus within managed care settings. In this study, patient satisfaction was used as an outcome measure and found to be significantly higher when social work to patient ratios were lower. Additionally, nephrology social work implementation of rehabilitation interventions was shown to be significantly higher when the social worker to patient ratio was lower. The availability of social workers to provide interventions that identify and ameliorate problematic circumstances that can contribute to poor patient outcomes is diminished by high caseloads.

Key Words: patient satisfaction, rehabilitation, social work staffing

# NEPHROLOGY SOCIAL WORK INTERVENTIONS AND THE EFFECT OF CASELOAD SIZE ON PATIENT SATISFACTION AND REHABILITATION INTERVENTIONS

## *Introduction*

There are three basic reasons to measure patient satisfaction: "1) satisfaction is the ultimate outcome of the delivery of health care, 2) satisfaction ratings provide useful information about the structure, process, and outcomes of care, and 3) satisfied patients and dissatisfied patients behave differently in terms of compliance with medical regimens" (Turnbull & Hembree, 1996). Unmet care needs and emotional distress are important variables in explaining patient dissatisfaction (Scholte et al, 1997).

Using patient satisfaction and the nephrology social worker's perception of their ability to provide certain interventions, this study attempts to establish a basis from which conclusions can be drawn regarding high patient ratios and nephrology social work interventions. The hypothesis of this study was that lower social work to patient ratios would increase patient satisfaction and increase rehabilitation interventions provided by the nephrology social worker.

## *Literature Review*

Patient satisfaction is an integral component of overall quality improvement plans (Turnbull and Hembree, 1996; Goldberg, 1994; Bergman, 1994) and is an important source of information about delivery, access and quality of health care (Ware et al, 1996; Rosselli et al, 1996). This information can be used to assess the process and structure (Zeigenfuss and O'Rourke, 1995) of patient-centered care which focuses on developing interventions that meet patient needs as perceived by the patient rather than the provider (Wakefield et al, 1994).

A growing number of health plans use patient satisfaction as an outcome measure (Rice, 1996; Sadler, 1995; Vichak, 1995; Ferrans et al, 1987) to determine reimbursement (Weingarten et al, 1995) and costs related to care. Patient outcomes can also be described in terms of quality of life, social functioning, mental functioning, physical functioning, and physiologic functioning. Psychosocial interventions can have a positive impact on these end-stage renal disease (ESRD) treatment outcomes (Rettig et al, 1997; Christensen et al, 1994) in addition to reducing medical costs (Duff & Vatour, 1989). Recent studies of ESRD patients show that perceptions of illness, life satisfaction, depression and adjustment to illness are correlated with social support (Kimmel et al, 1995) and are important factors in compliance (Hitchcock, 1992; House, 1988). These variables are potentially modifiable with directed psychosocial intervention. With appropriate caseloads and job descriptions nephrology social workers can provide services that support and maximize the psychosocial functioning, adjustment, and adaptation of patients and their families to the chronicity of ESRD treatment and its challenges (NASW/NKF Clinical Indicators, 1994).

The goal of the ESRD program is to "restore" patients to the highest level of functioning that is possible for them. Rehabilitation is identified as restoration of the whole person (LORAC, 1994). The desired outcomes of restoration of the whole person include vocational rehabilitation, physical rehabilitation, and psychosocial rehabilitation. Research shows that psychosocial factors play an

important role in the maintenance of employment among hemodialysis patients (Kutner, 1991; Antonoff & Mallinger, 1989; Ferrans, 1985; Sherwood, 1983) and that emotional well-being and rehabilitation are essential components of patient perceived quality of life (Ware, 1996). Additionally, patient's perceptions of the expectations of the medical team significantly influence their rehabilitation potential (Curtin et al, 1996). Access to timely and appropriate psychosocial interventions can greatly impact rehabilitation outcomes.

### ***Background***

Research shows that psychosocial risk factors which include aging, comorbid conditions, inadequate social support, inadequate resources and finances negatively impact medical treatment outcomes and mortality. The current study suggests that there are high psychosocial risk factors in the population responding and that timely and appropriate nephrology social work interventions are indicated. A patient satisfaction survey that measures the patient's satisfaction with social work services usually reflects the patient's level of satisfaction with their ability to access social work services. The patient's perception of how helpful the social worker has been in resolving or addressing issues of adjustment and psychosocial problems could also be measured (Cornell & Kitsen, 1995).

This study was prompted by two basic concerns of the North Texas Chapter of the National Kidney Foundation's Council of Nephrology Social Workers':

1. Concerns regarding less than optimal patient outcomes due to facilities having high social work to patient caseloads
2. Concerns regarding the realignment of social work tasks from clinical intervention towards more non-skilled tasks.

The need for empirical data that establishes the relationship between social work staffing and patient satisfaction as an outcome measure provides the rationale for this study. The study sought to determine whether patient satisfaction with social work services would be higher when caseload ratios are lower (<1:100). The study also looked at differences in high and low patient ratios with regard to rehabilitation interventions provided by the nephrology social worker.

### ***Design***

The design for the study was a natural experiment seeking to establish a relationship between the size of the nephrology social work caseload and the level of patient satisfaction for dialysis patients.

This design is appropriate when comparing the effects of different categories of a variable in a natural setting.

Subjects for the study were adult patients with end-stage renal disease receiving dialysis treatment in Texas and social workers providing intervention in dialysis centers in Texas. The facility sample for the study was drawn by using a stratified random sample which resulted in of 138 of the 229

dialysis centers in Texas. Five of these centers did not meet the criteria for this study (i.e. pediatric population), therefore; the total sample population would be 1330 patients if all responded.

Patient satisfaction surveys were mailed to the Director of Nursing of the selected centers with a cover letter requesting the survey be administered to the first five patients to arrive for dialysis on the early morning and mid-shift of a given day. Patients were given a cover letter with the questionnaire. The cover letter explained the study and stated that their participation was strictly voluntary and they would remain anonymous.

Social work staffing surveys were mailed separately to the social workers in the selected dialysis centers with instructions for each social worker in the facility to complete a survey. If one social worker per facility returned the survey, this would yield a sample population of 133 social workers.

A second mailing which included a rehabilitation questionnaire was mailed to the social workers that responded to the initial questionnaire approximately six months following the first mailing. In this second mailing, a total of 57 facilities received questionnaires for the nephrology social worker(s) to complete.

### *Instrumentation*

Three questionnaires were used to collect information. A patient satisfaction questionnaire (Appendix 1) was used to obtain information about patient agreement with social work roles, availability of the social worker to meet with patients, satisfaction with the amount of time spent with the patient, and demographic data. This questionnaire was adapted from a 1994 survey used to measure patient satisfaction (Siegal et al, 1994).

Social work questionnaires (Appendix 2) were used to obtain information about patient acuity and caseload served by the social worker and the amount of time spent in the functions of clinical intervention, case management, resource procurement, administrative/supervisory tasks, and non-skilled tasks. The initial survey was adapted from two previously completed surveys: 1) The Quality and Accessibility Study (CNSW, 1989) and 2) Kansas-Western Missouri Survey (Witten, 1995). Some changes were made based upon recommendations from the authors of these surveys. Other adaptations were made in order to gather specific data needed for this study.

Additionally, a subset of the Unit Self-Assessment Tool (USAT) (Appendix 3) was used to survey social workers who had returned the initial survey. The Unit Self-Assessment Tool, developed by the Life Options Rehabilitation Advisory Council (1997), allows ESRD facilities to assess their rehabilitation programming against a standard set of criteria. Through peer review, questions that seemed likely to relate to the nephrology social work role in rehabilitation were extracted. Equal questions were extracted in all three areas of the USAT--basic, intermediate, advanced.

### *Data Analysis*

Data from the initial two surveys was analyzed using the SPSS. Statistical tests included chi-square and *t* tests of the means. Significance levels were set at conventional  $\alpha$  .05. Hypothesis testing for the USAT included the use of *t* tests.

### *Results*

Patient satisfaction with the amount of time the social worker spent with the patient was statistically significant dependent upon the number of patients in the caseload ( $p < .05$ ). Patient satisfaction was statistically significant dependent upon how often the social worker was available ( $p < .01$ ).

A total of 444 patient surveys and 68 social worker surveys were returned. Of this total, 36 centers responded with both patient and social worker surveys. Eight of the social work surveys received were inappropriate for measuring caseload size (i.e. data was incomplete), but other data could be used such as patient acuity, etc. Three centers responded too late for patient surveys to be included.

Of those responding, 53% of social workers had caseloads  $>100$ . But in rural settings, 80% of those responding had caseloads of  $>100$ .

The results of this study regarding gender, race, and age are consistent with the United States Renal Data Systems reporting of this information (USRDS, 1997) (See Table 1). Patient acuity and psychosocial risk factors as noted by social workers responding (See Table 2) are comparable to previous studies measuring age, comorbid conditions, social support, indigency, and limited environmental support (CNSW, 1989; Witten, 1995).

A statistical significance was found related to caseload size and rehabilitation interventions ( $p < .05$ ). Of the rehabilitation questionnaires mailed, 60% were returned. One survey was not used due to incomplete data.

### *Discussion*

Support was obtained for the hypothesis that patient satisfaction is dependent upon the number of patients in a social worker's caseload. If caseloads were less than 100, patients reported being more satisfied.

If the social worker had more than 100 patients per full-time employee (FTE), less satisfaction with social work availability was found. Even though low numbers of patient-social worker matched responses were received, the data from all the randomly selected centers was very similar to the data from the matched centers and increases the likelihood that the responses are representative of the random sampled population.

Additionally, it is of concern that 80% of rural settings had caseloads of  $>100$ . Rural elders report a higher number of medical conditions, more functional limitations, and difficulty performing a



greater number of activities of daily living and intermediate activities of daily living tasks (Coward et al, 1994). Elders from small towns and rural communities have a higher rate of Medicare hospital discharges per 1,000 enrollees than do their counterparts in metropolitan areas (U.S. Senate, Special Committee on Aging, 1992). Sociodemographic characteristics of older persons who live in small towns and rural communities place them in a disadvantaged position relative to their urban counterparts. As a consequence, rural elders are at risk for poor health outcomes (Coward et al, 1994).

### ***Limitations of the Study***

Social workers from twenty-one centers in the random sample (16%) with caseloads over 100 did not respond to the survey. One center that did not respond wrote an anonymous letter relating administrative suspicion that the survey results might have an undesired regulatory impact later and had been asked not to complete survey.

Responses by patients may have been skewed by patient selection. It was found that even though directions specified that the social worker not be involved in giving the patient surveys, many did. Also, it is likely that Directors of Nursing handing out the survey would select independently functioning patients who could complete the surveys themselves. It is possible that these patients would have fewer psychosocial risk factors, thus, lessening the need for social work intervention. Additionally, several centers that did not participate in patient surveys related that authorization from corporate office was not received to complete the survey.

Even though surveys for patient satisfaction and social work functions were adapted from previous surveys, patient surveys and social work surveys may have not correlated well with each other to measure the impact of caseload size on the effectiveness of social work interventions. Research did not reveal previously developed instruments with established reliability and validity to measure ESRD patient satisfaction and social work interventions. The three instruments referred to were adapted to collect needed information.

### ***Implications for Further Study***

Masters-trained social workers possess the knowledge and skills to deliver the highest standard of care to the nephrology patient. It is believed that the number of patients for which a social worker has responsibility directly impacts the ability to provide that quality of care. Further research is needed to examine the relationship between ratios, interventions and outcomes. Nephrology social workers must take an active role in evaluating their own practices as well as researching areas such as the ones discussed in this article.

### *Conclusion*

Patient dissatisfaction and poor functional health and well-being have significant economic implications. Perceived unmet care demand and emotional distress are important variables in explaining dissatisfaction. Evidence exists that greater satisfaction with care increases the patient's compliance with treatment and results in better clinical outcomes (Rueben et al, 1992) and ability to achieve rehabilitation goals. It is forecasted that patient satisfaction will be used by payers (Medicare, managed care, and employers) as an economic outcome that reflects the indirect non-medical costs that are associated with either illness or care (Hull, 1998; Turnbull and Hembree, 1996; Rosselli et al, 1996).

Nephrology social workers serve as patient advocates in interdisciplinary team planning and interventions. Three points need to be focused upon to review of the quality and accessibility of nephrology social work services:

1. Patients have identified that access to a nephrology social worker is important (Siegal et al, 1994)
2. Patients have expressed concern over the decreased availability of social workers (Levinsky, 1993)
3. Inadequate social work staffing is a barrier to achieving optimal patient outcomes (Callahan et al, 1997; Davenport et al, 1993) that improve patient-perceived quality of life

This study contributes to the understanding of patient satisfaction as a relevant outcome measure for health care. Patients with ESRD have varied and numerous psychosocial needs that can impact patient perceived quality of life and rehabilitation across the life cycle. The availability of nephrology social workers to provide interventions that identify and ameliorate problematic circumstances that can contribute to poor patient outcomes is diminished by high caseloads.

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**Table 1**

**Comparison of USRDS Data and Texas Sample**

Ethnicity		USRDS	Texas Sample
American Indian		1.5%	1.6%
Asian/Pacific Islander		3.2%	.5%
Black		31.9%	38.5%
Caucasian (includes Hispanic)		62.4%	60.1%
Age			
0-19		1.8%	0
20-44		26.6%	
26-35			8.5%
36-55			39.9%
45-64		38.0%	
56-65			21.1%
66-80			25.2%
65-74		21.0%	
75 & >		12.6%	
Gender			
Male		54%	50.5%
Female		46%	49.5%

**Table 2**

**ESRD Patient Acuity**

<b>Acuity Factors</b>	<b># of patients</b>	<b>percentage</b>	<b>total # of patients</b>
Age 60 or over	2356	51%	4598
Diabetic	1956	44%	4449
Nursing Home	195	4%	4598
Age 18 or younger	8	.01%	4598
Inadequate social support	975	22%	4518
Financially indigent	1821	40%	4598
Need medication assistance	1143	25%	4518
Need transportation services	1348	29%	4598

## Appendix 1

### PATIENT SURVEY PLEASE MARK THE ANSWER THAT BEST DESCRIBES YOUR FEELINGS

My social worker is available to help me when I have complaints or concerns about my dialysis treatment.

strongly disagree	disagree	agree somewhat	agree	strongly agree	does not apply to me
-------------------	----------	----------------	-------	----------------	----------------------

I am satisfied with the amount of time my social worker spends with me.

strongly disagree	disagree	agree somewhat	agree	strongly agree	does not apply to me
-------------------	----------	----------------	-------	----------------	----------------------

I feel comfortable talking with my social worker about problems I need help with.

strongly disagree	disagree	agree somewhat	agree	strongly agree	does not apply to me
-------------------	----------	----------------	-------	----------------	----------------------

My social worker has helped me understand how dialysis may affect my life.

strongly disagree	disagree	agree somewhat	agree	strongly agree	does not apply to me
-------------------	----------	----------------	-------	----------------	----------------------

My social worker helps me talk with doctors and other staff members.

strongly disagree	disagree	agree somewhat	agree	strongly agree	does not apply to me
-------------------	----------	----------------	-------	----------------	----------------------

My social worker has helped me think about returning to work.

often	sometimes	once	never
-------	-----------	------	-------

My social worker has talked to me about returning to activities I enjoy.

often	sometimes	once	never
-------	-----------	------	-------

I know how to contact my social worker if I need help.

yes	no
-----	----

A renal social worker should talk with patients about how dialysis may affect their way of life.

do not agree	agree a little bit	agree	agree a lot
--------------	--------------------	-------	-------------



A renal social worker should talk with patients about continuing and returning to family activities, exercise, and work.

do not agree	agree a little bit	agree	agree a lot
--------------	--------------------	-------	-------------

A renal social worker should help patients work out any complaints or concerns about their treatment.

do not agree	agree a little bit	agree	agree a lot
--------------	--------------------	-------	-------------

Please provide the following information about yourself:

Age: ☐ 18-25 ☐ 56-65  
☐ 26-35 ☐ 66-80  
☐ 36-55 ☐ Over 80

Sex: ☐ Male ☐ Female

Ethnicity: ☐ American Indian  
☐ Asian/Pacific Islander  
☐ Black  
☐ Hispanic  
☐ White  
☐ Multiracial  
☐ Other

How long have you been receiving kidney dialysis treatments?

☐ less than 6 months  
☐ 6 months to 1 year  
☐ 1 to 3 years  
☐ 3 to 7 years  
☐ 7 to 15 years  
☐ over 15 years

About how often is your social worker available to talk with you?

☐ at least 1 time per week

- \_\_\_\_\_ 2 times a month
- \_\_\_\_\_ 1 time per month
- \_\_\_\_\_ 1 time every 2 months
- \_\_\_\_\_ 1 time every 3 months

Appendix 2  
**SOCIAL WORK STAFFING AND OUTCOMES PROJECT**

1. How many patients do you currently serve in this facility?  

<input type="checkbox"/> Center Hemo	<input type="checkbox"/> Home Hemo
<input type="checkbox"/> CAPD	<input type="checkbox"/> CCPD
<input type="checkbox"/> Transplant	<input type="checkbox"/> Pre-ESRD Inpatients/Outpatients
<input type="checkbox"/> ESRD Inpatients	<input type="checkbox"/> Other _____
2. How many patients have been admitted to your caseload between July 1, 1996 and December 31, 1996? (Include expired or discharged patients also) \_\_\_\_\_
3. What **percentage** of time per month do you spend in this facility performing the following:  
  
☐ Clinical Intervention  
    Psychosocial assessment and treatment planning  
    Counseling and support of patients and significant others  
    Groupwork  
    Crisis Intervention  
    Patient/Family Education  
  
☐ Case Management  
    Risk Management by intervening with patients and families who are dissatisfied with their care  
    Quality Management Activities  
    Interdisciplinary Collaboration  
    Discharge/transfer planning  
    Documentation  
    Patient Advocacy  
  
☐ Administration/Supervisory Activities  
    Consultation  
    Professional Development  
    Provide Inservice Education  
    Patient/Staff Mediation  
  
☐ Resource Procurement  
    Assistance in identifying and obtaining non-medical community resources  
    Assistance in identifying and obtaining entitlement benefits (Medicare, Medicaid, QMB, KHC)  
    Assistance in identifying medical rehabilitation resources  
    Collaboration towards resource development  
  
☐ Non-skilled tasks  
    Admission paperwork

Transient arrangements

4. How many hours do you work in this facility each week? \_\_\_\_\_
5. How many dialysis facilities do you serve? \_\_\_\_\_  
How many miles apart, if applicable? \_\_\_\_\_  
Do you travel to more than one facility in a given day? \_\_\_\_\_
6. What is the patient acuity at this facility (calculate, using numbers rather than percentage, using **only your caseload**)?

\_\_\_\_\_ # age 60 or older

\_\_\_\_\_ # diabetic

\_\_\_\_\_ # in nursing homes  
regularly

\_\_\_\_\_ # age 18 or younger

\_\_\_\_\_ # with inadequate social support

\_\_\_\_\_ # financially indigent

\_\_\_\_\_ # needing help with medications

\_\_\_\_\_ # needing transportation services

7. Does your facility encourage social work professionalism in the following ways:

Reimbursement of education expenses

none    partial    full

Payment of continuing education expenses

none    partial    full

Time off work allowed for educational purposes

none    partial    full

Payment of national professional dues

none    partial    full

Payment of licensing fees

none    partial    full

8. Are you a member of the local chapter of the Council of Nephrology Social Workers?  
Yes    No

9. Are you a national member of the Council of Nephrology Social Workers?  
Yes    No

10. Please describe your facility (circle one in each category):

hospital based

or

free standing

for profit

or

not for profit

11. Please describe your facility (circle one):

urban (over 2,500 in area population)

rural (under 2,500 in area population)

12. Please describe your educational background:

BSW    MSW    DSW    PhD    Other, specify \_\_\_\_\_

13. Please describe your licensure:

LSW    LMSW    LMSW-ACP    Other, specify \_\_\_\_\_

### Appendix 3

PLEASE MARK EACH ITEM WITH A "Y" FOR YES, OR "N" FOR NO  
AND RETURN IN THE ENCLOSED ENVELOPE BY **NOVEMBER 14, 1997.**

(Answer "yes" ONLY to the items that YOU personally provide for **your** patient caseload at this center)

\_\_\_ Do you provide occasions for talks with patients about positive outcomes of other patients (without violating patient confidentiality)?

\_\_\_ Do you provide written educational materials to patients/families/friends?

\_\_\_ Do you provide educational videos to patients/families/friends?

\_\_\_ Do you have patient support groups that are run by a facilitator?

\_\_\_ Do you perform systematic and routine evaluation and set goals for ALL patients?

\_\_\_ Do you teach families how to support/what to expect from renal patient?

\_\_\_ Do you have a regular program of predialysis or early (within the first 6 weeks on dialysis) intervention to encourage positive patient attitudes and expectations?

\_\_\_ Do you actively encourage and provide assistance for patients' participation in their dialysis and other treatments in order to encourage their independence?

\_\_\_ Do you track the outcomes or results of your encouragement-related efforts?

\_\_\_ Do you have a special orientation program for new patients?

\_\_\_ Do you have educational programs for patient families or other social support persons?

\_\_\_ Do you provide educational programs for members of the health care team?

\_\_\_ Do you sponsor or provide any educational programs for potential or present employers of dialysis patients?

\_\_\_ Do you routinely and repeatedly offer educational materials to patients?

\_\_\_ Do you ever have any special "presentations" made by staff or guest speakers?

\_\_\_ Do you provide educational classes outside of dialysis time?

\_\_\_ Do you provide any sort of evaluation for literacy level of your patients?

\_\_\_ Do you have a *continuing* educational program for established patients?

\_\_\_ Do you have brochures/literature about renal exercise routinely available?

\_\_\_ Do you have any videos re: exercise available in the unit or for home use?

\_\_\_ Do you sponsor or give awards or other recognition for patients' efforts toward improving physical functioning?

\_\_\_ Do you sponsor group exercise programs that are offered during off-dialysis time?

\_\_\_ Do you have any fitness apparatus or exercise equipment available at the unit?

\_\_\_ Do you regularly refer patients for OT and/or PT evaluations and

treatments?

- \_\_\_\_\_ Do you provide for any kind of exercise programming outside of the dialysis unit that includes evaluation and individualized planning?
- \_\_\_\_\_ Do you have in-center, organized group fitness activities during dialysis?
- \_\_\_\_\_ Do you track the outcomes or results of your exercise-related dialysis?
- \_\_\_\_\_ Do you inform patients about choices of treatment modalities to accommodate their work and life interests?
- \_\_\_\_\_ Do you provide information for families about patients' potential to continue working and the benefits of working?
- \_\_\_\_\_ Do you regularly do "informal" screening for employment status or potential?
- \_\_\_\_\_ Do you have an ongoing relationship with the VR agency to facilitate patients' retraining or job placement?
- \_\_\_\_\_ Do you automatically refer all working-age patients to VR?
- \_\_\_\_\_ Do you have any in-center employment support groups?
- \_\_\_\_\_ Do you do formal screening of patient for employment status/potential?
- \_\_\_\_\_ Do you have any mechanism or program to connect patients with jobs?  
(Not TRC)
- \_\_\_\_\_ Do you provide any early interventions (predialysis or within first 6 weeks) to help patients keep their jobs?
  
- \_\_\_\_\_ Do you do regular assessment of patients' satisfaction with their levels of functioning or with their rehabilitation status?
- \_\_\_\_\_ Do you perform routine rehabilitation intake assessments of new patients using standardized instruments?
- \_\_\_\_\_ Do you track the effects of your rehabilitation efforts?

### AUTHOR'S NOTE

Mary Beth Callahan, ACSW/LMSW-ACP has worked in nephrology social work since 1984. She is currently employed by Fresenius Medical Care--North America at Farmers Branch Dialysis, 2280 Spring Lake Rd, #110, Farmers Branch, TX 75234). She is Chair of the National Kidney Foundation's Council of Nephrology Social Workers and has a special interest in rehabilitation and quality of life measurement.

Marianne Moncrief, LMSW, has two masters degrees--in Gerontology and Social Work. Marianne has worked for 12 years in the fields of long term care, retirement housing, and home health care. She has worked in nephrology in the Dallas area since 1994. She is currently employed by Fresenius Medical Care--North America at the Richardson and Towngate Dialysis Centers. Marianne served as the North Texas Council of Nephrology Social Workers Research Chair for this project.

Judi Wittman, LMSW, has worked in nephrology in the Dallas area since 1994 and was employed by Fresenius Medical Care--North America at the Oak Cliff Dialysis Center. During the time of this research project, Judi was Chair of the North Texas Council of Nephrology Social Workers.

Marie Maceda, LMSW, has worked in nephrology in the Dallas area since 1994 and is currently employed by Fresenius Medical Care--North American at the Village II Dialysis Center. Marie has served as Vice Chair of the North Texas Council of Nephrology Social Workers.

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Established in 1969

American Nephrology Nurses' Association

May 5, 2005

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The Honorable Mark McClellan  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3818-P  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: Comments on Conditions for Coverage for End Stage Renal Disease  
Facilities; Proposed Rule; CMS-3818-P**

Dear Administrator McClellan:

The American Nephrology Nurses' Association (ANNA) is the professional nursing organization representing over 12,000 registered nurses (RNs) who care for patients with chronic kidney disease. The majority of our members practice in outpatient dialysis settings in a variety of roles including the provision of both direct and indirect care to patients on dialysis, management, staff training and development, and home dialysis training and support. ANNA's members represent those healthcare professionals in the closest and most frequent contact with individuals with ESRD, and as such, are heavily invested in the Proposed Rule revising the Conditions for Coverage for End Stage Renal Disease Facilities and the changes it suggests in how their practice setting will be regulated and how their patients will receive care through the Medicare program.

**Background**

ANNA wholeheartedly supports the Agency's fundamental shift in its regulatory approach to create a patient outcome-oriented environment. Suggestions on how it could be improved upon, what might be added or deleted, and which requirements are critical to patient care and safety will form the basis of the following comments.

Before addressing the specifics of the Proposed Rule itself, we think it is important to comment that we noted a number of requirements in the Rule that are not consistent with Medicare payment policies. We believe it is incumbent upon the Agency to only establish regulatory requirements that are consistent with program payment rules or to change payment policies to support the rules. This problem was acknowledged with regard to the recommendation for Hepatitis C screening, but not with other provisions. We comment on these areas individually, but also wanted to call attention to them in a global context.



## **Special procedures for approving ESRD facilities**

**§488.60:** ANNA is concerned that facilities applying for initial approval may not have the data requested by this rule, other than an attestation of compliance and of having qualified staff.

### **Definitions**

**§494.10:** ANNA believes that the definition of “home” should include institutional settings such as a nursing facility (NFs) and skilled nursing facility (SNFs), if that is the patient’s permanent residence.

ANNA requests the inclusion of definitions of “direct supervision” and “immediate supervision.” Direct supervision is cited at 494.140(e)(3). It is important to include a definition of immediate supervision and to be clear about the distinction between the two. We suggest that “immediate supervision” means the supervisor is *actually observing* the task or activity as it is performed and “direct supervision” means the supervisor is *on the premises but not necessarily immediately physically present* where the task or activity is being performed. We think this is consistent with the intent of the Proposed Rule but these definitions will make it more clear and must be included in the Final Rule to avoid problems at the facility level in determining compliance with some of the rules.

### **Infection Control**

ANNA agrees with the proposal to establish Infection Control as a separate condition for coverage.

ANNA supports the inclusion of the Healthcare Infection Control Practices Advisory Committee's (HICPAC) guidelines entitled "Hand Hygiene in Healthcare Settings." In its position statement on Vascular Access and in its Standards of Practice, ANNA has recognized the "Guideline for Preventing Intravascular Device-Related Infections" as the appropriate standard of care. We encourage CMS to do likewise in the Final Rule.

Regarding Hepatitis C screening, it is unfortunate that the Proposed Rule makes an exception to the CDC recommendations in this regard. We understand that dialysis precautions *should* be sufficient to prevent the spread of Hepatitis C, but we are also aware that the intra-facility spread of hepatitis C is well documented and that screening patients and staff at baseline and at reasonable intervals, such as semi-annually as CDC recommends, would alert the facilities to significant breaks in the implementation of dialysis precautions. We believe this is an instance where a negative outcome should trigger investigation and stimulate practice correction and are suggesting later in this response that Infection be added to the performance components of the QAPI program. ANNA appreciates the Agency’s recognition that Medicare payment policy is not consistent with CDC recommendations in this regard and believes it is unfortunate that payment policies do not consistently support the establishment of good policy for the beneficiaries.

ANNA agrees with incorporating the CDC “Recommendations for Preventing Transmission of Infections among Chronic Hemodialysis Patients” and the guidance that staff members caring for HbsAg-positive patients should not care for HBV-susceptible patients at the same time if the definition of “HBV-susceptible” is “an individual who has Hepatitis B antibodies < 10.”

**§494.30(a)(1):** This language requires that items that cannot be cleaned and disinfected should be dedicated for use only by a single patient. Blood pressure cuffs are a good example of such items. Disposal of these cloth covered cuffs after patient use is not current practice and, while it may seem highly desirable, there are no cost effective disposable blood pressure cuffs available. Current practice is to surface clean the blood pressure cuff with an approved disinfectant. There are both cost and logistical considerations in requiring a blood pressure cuff for each patient. Storage of these cuffs and the cost of purchasing a cuff per patient make it unrealistic in the dialysis setting. Units with a large patient census would not necessarily have storage space for the cuffs. The challenge of inventing an impermeable, disposable, low cost covering for the BP cuff or inventing another means of blood pressure monitoring is the conceptual alternative to the current practice but is not available at this time.

The same section proposes that dialyzers and blood tubing that will be reprocessed have caps placed on ports and lines clamped prior to placing these in a leak proof container for transport to the reprocessing area. We would suggest changing the language to clarify that “if placed into a container, that container must be leak proof.” The practice in some facilities is to transport the dialyzer and tubing to the reuse area without the use of separate containers. Requiring a container introduces another piece of equipment that must be purchased and cleaned.

**§494.30(b)(2):** In keeping with the outcome orientation of the Proposed Rule, ANNA does *not* agree with a requirement for an infection control officer and believes that facilities should determine such a need through their QAPI program and have therefore recommended that Infections be a required performance component of the QAPI program. While we realize that infections are a major concern, we believe that the QAPI focus should provide sufficient attention in this area.

With regard to the existing infection control standard at **§405.2140(b)**: ANNA agrees with the proposal to delete the redundant requirement regarding reuse; and with regard to the existing standard at **§405.2140(c)**: ANNA agrees with the deletion of the “written policy” requirement.

## **Water Quality**

ANNA agrees with the proposal to establish Water Quality as a separate condition for coverage.

ANNA agrees with CMS that AAMI is the appropriate authority on water and dialysate quality and believes that the condition should endorse the entire AAMI Dialysate Standard (RD52:2004) as it is the most current standard to guide the user in selecting, maintaining, operating and monitoring water treatment components and the one most relevant to dialysis facilities. References to older AAMI documents related to water treatment would not be needed.

Incorporating all of RD52:2004 would require, among other things:

(1) a reduction in the allowable dialysate colony counts from 2000 cfu/ml to 200 cfu/ml, which would be a significant step toward more pure dialysate, which ANNA believes is important, given evidence demonstrating a link between ultrapure dialysate and improved patient outcomes, reduced inflammation and other disease markers; and

(2) two carbon tanks in series, with a minimum of 10 minutes Empty Bed Contact Time. We believe that most of the facilities in the US have already implemented this system to prevent the exposure of patients to chloramine.

With regard to incorporating such documents by reference, we support a more rapid adoption process to update these regulatory requirements as the AAMI recommendations are updated to reflect changes in understanding and knowledge related to dialysis water and dialysate quality.

**§494.40(c)(2):** ANNA suggests clarifying the language here. The proposed language states, “The water from the exit port of the first component or carbon tank which removes chlorine/chloramine is tested for chlorine/chloramine levels, at a minimum, before each patient shift or every 4 hours, *whichever is shorter*, during operation of the water treatment system.” To provide clarity and maintain consistency with AAMI RD52:2004, the dialysate standard, we suggest the Final Rule read, “The water from the exit port of the first component or carbon tank which removes chlorine/chloramine is tested for chlorine/chloramine levels *before each patient shift or at least* every 4 hours during operation of the water treatment system.”

**§494.40(c)(2)(ii):** We suggest the rule should clearly state that using one test of sufficient sensitivity for total chlorine with a result of  $<0.10$  is acceptable, rather than requiring two separate tests.

Please note that, with incorporation of the entire AAMI Standard Dialysate for Hemodialysis (RD52:2004), 494.40(c)(2) and (c)(2)(ii) could be omitted, as these issues are addressed in that standard.

## **Physical Environment**

Consistent with the statement on page 6201 of the Preamble that “patients should be in view of staff at all times during the treatment to ensure safety,” we suggest this language be incorporated as a standard at §494.60.

**§494.60(c)(2)(i) and (ii):** ANNA is sympathetic to the problem of maintaining adequate and comfortable temperatures for the majority of the patients and we believe that nurses already strive to keep their patients comfortable, as well as safe, during dialysis, but we do not think it is consistent with an outcome focus that these provisions be included in the final rule.

**§494.60(d):** With the current international concern about bioterrorism, ANNA believes the final rule should address this. CMS could require dialysis facilities to incorporate bioterrorism preparedness procedures in their disaster plan, including such things as a means of communication with the local civil defense organization regarding transportation routes in case of evacuations, requiring patients to have at least 7 days of critical medications on hand, etc.

Such things would be necessary in case of limited access to roads or mass transport systems, water supplies, pharmacies, grocery stores, etc.

**§494.60(d)(3):** ANNA agrees with CMS that defibrillators should be required in all dialysis facilities, given the incidence of cardiac disease in the dialysis patient population. We prefer language that mandates automated external defibrillators (AEDs), *especially* in small, predominantly rural, dialysis facilities that might not have readily available emergency medical systems. The only exception could be facilities located inside hospitals that have ready access to the hospital's emergency response team. We agree that dialysis nursing staff must be trained in the proper use of emergency equipment and emergency drugs, and note that non-automated defibrillators require staff to be certified in Advanced Cardiac Life Support (ACLS). ACLS courses are not readily available to dialysis facilities, are time consuming and costly. If CMS requires non-automated defibrillators, this would also require that there be qualified staff on-duty at all times to operate those defibrillators. This is not practical in the current environment; we support the requirement of AEDs in the final rule.

**§494.60(e):** ANNA suggests that provisions of the Life Safety Code (LSC) apply only to new facilities, those built after the final rule is implemented. Dialysis facilities are often located in buildings that do not have sprinklers. Requiring such a facility to have sprinklers installed would be a prohibitively costly expectation. Enforcement of other provisions of the LSC may require major, costly modifications to a building that currently houses a dialysis facility, or lead to facility closure or relocation.

### **Patients' Rights**

ANNA suggests a different approach to this entire section. We believe that, as is true for all of us, rights are accompanied by responsibilities. While we recognize that CMS does not regulate patient behavior, we would appreciate a requirement that patients be informed of their responsibilities, to include, at a minimum, coming to scheduled treatments, being on time, following dietary and fluid restrictions, and informing the care team if they are unable to have prescriptions filled or to make physician appointments.

**§494.70(a)(5):** ANNA strongly agrees with the sentiment expressed in the Proposed Rule that patients must be informed about and participate in all aspects of their care, while recognizing that a facility cannot require their patients to participate in the care process. We suggest, however, that the wording "if desired" should be changed to "if capable" to demonstrate an expectation of patient participation in care. We believe that if patients and families are expected to participate they will learn more readily and will be better able to monitor received care as well as assume varying degrees of self-management. This is both a safety and a quality of life issue, and registered nurses are eager to assess for self-management capability, to teach self-management skills to capable patients, and to support patients in self-management.

**§494.70(a)(6):** The options presented should be stated more broadly to allow for new modalities that may emerge; further, the list should include the option for "No Treatment."

**§494.70(a)(13):** ANNA agrees with the strengthened requirements for an internal grievance process. Most facilities already post grievance procedures in the lobby.

## Patient Assessment

ANNA agrees wholeheartedly with CMS that the inclusion of a minimum set of assessment criteria is inconsistent with the agency's stated goal of eliminating unnecessarily prescriptive and process-oriented requirements and we therefore oppose the inclusion in the final rule of a condition on Patient Assessment. CMS seems to agree that there is little need for this in the Preamble, when it states that expanding the existing requirements with regard to patient assessment should not impose any additional burdens on facilities because quality-oriented facilities already routinely perform such assessments upon initiating treatment, and most facilities already have this information in the medical record. It is unclear what evidence of need is driving this requirement, which is in direct opposition to the Agency's new fundamental shift in approach to regulating. As professional nurses we do not need to have spelled out in regulation how to conduct an assessment on a patient with renal failure.

In order to develop plans of care, each professional must go through a process that includes data gathering and begins with an assessment – of the patient and of objective data related to the patient. Dialysis professionals have been doing this for over thirty years in developing care plans under the existing regulations. Federal oversight is unnecessary to ensure the professional nurse uses the nursing process, which is the foundation for all nursing care.

In the Preamble, CMS states it believes the patient assessment and patient care plan are inextricably linked, with which we wholeheartedly agree and which bolsters our suggestion that the assessment should be eliminated as a condition and subsumed under Plan of Care, since an assessment is fundamental to the establishment of any such plan.

Therefore, ANNA proposes that the language identifying the interdisciplinary team at §494.80 be moved to the introductory language at §494.90 and that §494.80(a) be deleted. The requirement at §494.80(b) regarding the frequency of assessments for new patients and the language at §494.80(d) regarding patient reassessment should be incorporated into §494.90(b) under the implementation of the plan of care. We believe the language at §494.80(c) related to assessment of treatment prescription is already addressed at §494.90(a)(1).

With regard to the language identifying the members of the interdisciplinary team currently at §494.80, ANNA requests clarification of the first sentence with regard to the inclusion of "...the patient (if the patient chooses) or the patient's designee..." We have two concerns here. First, in the final rule please clarify whether this means either the patient or the patient's designee **MUST** participate, keeping in mind that some patients are not willing and some of them have no designee. Secondly, we would like to see the wording changed to "if the patient is capable." If the patient is capable but refuses, it is not appropriate to require a designee to take his place. However, if the patient is incapable, a surrogate is appropriate. The use of the word *surrogate* would make this clear.

Understanding that the list of members of the interdisciplinary team is presented as a minimum requirement, ANNA suggests including "non-physician provider" (which can be an advanced practice nurse or a physician's assistant, as recognized in Medicare statute) as an optional part of the team. These professionals are recognized providers, are increasingly used in nephrology settings, and can represent the patient's physician to the extent allowed by law in any state.

With regard to proposed §494.80(d)(2)(iv), which we are suggesting be moved to §494.90(b), ANNA has some concerns with this criterion for instability: “Poor nutritional status, with unmanaged anemia and inadequate dialysis.” We believe that documented poor nutritional status is appropriate for this category, but do not believe it should be linked with unmanaged anemia and inadequate dialysis. Since there is already a proposed requirement for inadequate dialysis to be assessed on an ongoing basis, we suggest that (iv) should state “Poor nutritional status” and (v) should be added and should state “Unmanaged anemia.”

### **Plan of Care**

ANNA supports combining the elements of the existing long-term program into the patient plan of care.

With regard to the proposal that outcomes specified in the patient plan of care must allow the patient to achieve “current evidence-based community-accepted standards,” we want to express concern that, while we support requirements for facilities to organize their work in general, and to plan patient care in particular, with the goal of patients meeting at least minimum threshold values of established standards of care, we find this language in the proposed rule too vague. Specifically, “community-accepted” is not appropriate language for the Final Rule. Such language could allow facilities across the country to treat patients differently in terms of the outcomes expected of them.

We suggest more specific language that would recognize The National Kidney Foundation’s Kidney Disease Outcome Quality Initiative (K/DOQI) or other standards that may be developed by recognized healthcare standard-setting organizations through a rigorous scientific process that has involved experts in the renal field and that have been endorsed and embraced by the renal community. Currently these standards are the K/DOQI guidelines, so we have chosen to reference them in our comments that follow.

**§494.90(a):** ANNA suggests that “bone disease management” should be incorporated into the plan of care and read: “The interdisciplinary team must provide the necessary care and services to achieve a stable skeleton and avoid the consequences of secondary hyperparathyroidism. Calcium, phosphorous and other laboratory tests related to achieving these outcomes should be measured as recommended in clinical performance measures and minimal thresholds should be met.” The Final Rule should include additional language that references the specific minimum K/DOQI standard(s) the Agency intends to be met for bone disease management.

**§494.90(a)(1):** The Final Rule should include additional language that references the specific minimum K/DOQI standard(s) the Agency intends to be met for hemo and peritoneal dialysis adequacy.

**§494.90(a)(2):** ANNA believes that albumin is a poor measure of patient nutritional status as it is affected by fluid overload, infection, liver disease, inflammatory conditions etc. A global assessment tool taking into account several markers should be used. We would suggest using Normalized Protein Catabolic Rate (NPCR) as an additional outcome measure.

We note the language of the rule requires the interdisciplinary team to “provide the necessary care and services to achieve and sustain an effective nutritional status” and must point out that there is no covered Medicare benefit for any “care and services” that would achieve this end. The team can monitor nutritional status but is handicapped in affecting any outcome measure that would be decided upon. This has been well documented in the Clinical Performance Measure project that has shown no improvement in serum albumin since the initiation of the Core Indicators Project in 1994. This reality should be reflected in the construction of the Final Rule, and the language in the first sentence must be limited to read, “The interdisciplinary team must monitor the patient’s nutritional status.”

**§494.90(a)(3):** The Final Rule should include additional language that references the specific minimum K/DOQI standard(s) the Agency intends to be met for anemia management.

According to the K/DOQI guidelines, patients with hemoglobin and hematocrit in the range specified in the Proposed Rule are evaluated for cause and appropriate treatment for their anemia, including erythropoietin therapy. The language here should be expanded to include these actions. We must also comment here that Medicare payment policy runs contrary to this goal, in that erythropoietin cannot be initiated on a patient who was not treated with erythropoietin prior to beginning dialysis therapy until his/her hemoglobin reaches 10gm/dL. We reiterate that these regulations should be consistent with Medicare payment policies or that payment policies should be changed to support these regulations.

**§494.90(a)(4):** ANNA agrees that the interdisciplinary team must provide the necessary care and services to achieve and sustain vascular access for all patients, but we question how facilities will be reimbursed for the required “*monitoring* of arteriovenous grafts and fistulae for stenosis.” Monitoring by means of frequent physical examination as per the K/DOQI guidelines is certainly a necessary expectation but, if in this context, “monitoring” *means* mechanical surveillance such as transonic flow measurements, there is no Medicare reimbursement for such services. The only “monitoring” of a vascular access that could have been envisioned when the composite rate payment was developed over three decades ago was done by a professional with eyes, ears (stethoscope), and fingertips. If frequent physical exam is what is meant by monitoring in §494.90(a)(4), ANNA has no problem with it, but that should be made clear. If the intent is more than that, the requirement should be deleted from the Final Rule, unless payment policy can be changed to allow reimbursement for more sophisticated “monitoring.”

It would be ideal to have a vascular access coordinator (RN) on the interdisciplinary team. We believe that such a role would be very cost effective in a globally-capitated disease management system, but doubt that many facilities could hire a dedicated vascular access coordinator in the current reimbursement environment.

**§494.90(a)(5):** ANNA agrees that the transplant status must be part of the plan of care condition and agrees with CMS that the transplant surgeon need not be involved with the facility interdisciplinary team unless a possible candidate has been identified. ANNA shares CMS’ concern that all appropriate potential transplant recipients be referred and followed, but points out that such referral is the responsibility of the patient’s attending nephrologist, who is not an employee of the facility. We further agree that in cases when the patient meets the transplantation criteria but declines referral, there must be documentation in the patient plan of care that the patient has made an informed decision to decline renal transplantation.

**§494.90(a)(6):** ANNA applauds the rationale in the preamble for rehabilitation and strongly supports the philosophy of self-management. Unfortunately the current caseloads for all members of the interdisciplinary team plus the acuity level of the patients make this goal unachievable. We believe that the interdisciplinary team must assist the patient in achieving the level of productive activity he/she desires by providing educational materials and referrals to community services. Physical and occupational therapists would be needed to implement, monitor, and evaluate exercise regimens. Except for making appropriate referrals, ANNA believes this requirement goes beyond the scope of the role of a dialysis facility and suggests that it be deleted from the list of minimum elements in the plan of care and that appropriate referrals be addressed under Social Services. In relation to the schooling needs of pediatric patients, again this would be evaluated during the psychosocial assessment but it is beyond the scope of the interdisciplinary team of a dialysis facility to provide for the general education of these patients. However, the team needs to assure that the dialysis schedule and related appointments of patients attending school are tailored to meet their needs.

**§494.90(b)(2):** ANNA believes that the timeframe for implementation of the plan of care for new patients should be measured by the number of treatments rather than the number of days because of the potential for missed treatments. Therefore, if the care planning process is completed in 21 days or 9 treatments, whichever is longer, implementing the plan of care by the conclusion of the 12<sup>th</sup> treatment provides a more suitable timeframe for the patient starting thrice weekly hemodialysis. We believe 30 days would suffice for the peritoneal dialysis patient. Once established, a plan of care is a dynamic document, changing as the patient's needs and outcomes change, but we agree with CMS that the plan should be formally revisited within three months of initial establishment.

**§494.90(b)(3):** This goes without saying, as it is a normal element of the care planning process. Registered nurses learn this early in their education and it does not belong in federal regulation.

**§494.90(b)(4):** While ANNA agrees that monthly interactions between patients and their physician are desirable, we do not believe the dialysis facility can be expected to ensure that all patients are seen by a physician at least monthly. Furthermore, we believe it is highly inappropriate for CMS to suggest requiring one provider to monitor another provider that Medicare is precluded by statute from regulating. The first sentence of Title XVIII, Section 1801, [42 U.S.C. 1395] states: "Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person." **ANNA strongly suggests that the language at (b)(4) be eliminated from the Final Rule and further suggests that this language is no longer necessary given the recent changes in the physician's MCP payment.**

**§494.90(c):** ANNA agrees that the interdisciplinary team or, more specifically, a designated member of the team, will be responsible for tracking the results of each kidney transplant referral until the patient evaluation is complete. We suggest that, since the proposed conditions of participation for transplant centers published in the Federal Register on February 4, 2005, require those centers to notify a patient's usual dialysis facility of the patient's transplant status post referral, and about any changes in their status, that this should be reflected in the final rule. We agree that the dialysis facility should notify the transplant center of changes in the clinical status



status of patients seeking transplantation. We recognize that when such changes are not communicated in a timely manner, unnecessary delays in the organ placement process may be incurred, potentially negatively impacting the transplant outcome. Recognizing the need for timeliness, we would suggest requiring notification of the transplant center of any change in the patient's status, rather than on any prescribed frequency. We would also like to suggest that secure internet access to the transplant center data base, which could be limited to the dialysis facility provider number and only to that facility's listed patients, would be an efficient way for the dialysis unit to monitor the waiting list as well as to alert the transplant center about changes in a patient's clinical status.

**§494.90(d):** ANNA supports the requirement for a patient education program. Nurses are teachers and we know that the informed patient is more likely to self-monitor and self-manage to the fullest extent possible. To add more substance to other areas in the Conditions, ANNA strongly suggests that (1) education and training on the risks, benefits and outcomes of various access types be included here because patients have the right to know the risks and benefits of each type of vascular access, particularly of the one they are currently using; and (2) "advance care planning" be added here since patients should not only be informed about their right to establish an advance directive at initiation of therapy, but they should also receive ongoing education about the importance of this as part of the plan of care and their participation in it.

### **Care At Home**

**§494.100:** ANNA strongly agrees that home dialysis patients receive the comparable quality of care and attention that the in-center patient receives.

**§494.100(a)(2):** ANNA agrees that initial home training of the patient and caregiver should be conducted by a qualified registered nurse and we agree with the qualifications.

**§494.100(a)(3):** ANNA agrees with CMS that specifying the topics for a training program appears to be inconsistent with the goal of reducing the process-oriented requirements and therefore opposes their inclusion. We question what evidence exists that led the agency to prescribe the elements of training, in direct opposition to the expressed new fundamental shift in approach to regulating. Nephrology professionals can be expected to design and carry out home training as they have for the past thirty-five years.

**§494.100(c):** Most of the requirements in this standard are already required of the facility with respect to ALL patients receiving care and services through the facility; therefore, ANNA does not see the need to restate them in this section. The structure seems to distinguish the home dialysis patients from the facility's entire population, when the stated goal is to provide equivalent services to the home dialysis population. We suggest the following: §494.100(c)(1)(i) and (ii) remain as is and the other subsections be deleted as they are not necessary. §494.100(c)(2) is also unnecessary as the facility will maintain a medical record for its home patients and, as stated, §444.330(a)(2) requires Durable Medical Equipment (DME) suppliers to provide the facility with a record of items and services it has provided to home dialysis patients who are being supported by the facility.

With regard to dialysis of residents of a NF or SNF or other institutional settings, ANNA agrees with the designation of such institutional settings as a patient's "home" if that is their permanent residence. ANNA is pleased to see the discussion of issues related to dialyzing the frail institutionalized elderly included in the Preamble, but notes there is nothing in the Proposed Rule about this. We take that as an invitation to continue to communicate with the Agency about this important subject since the incidence of ESRD is highest in the age groups that predominate in these types of settings.

ANNA also believes the modality of choice for the frail elderly should be peritoneal dialysis, as is the case in many other countries, and encourages the Medicare program to develop payment policies that support that goal.

That said, ANNA believes the dialysis facility approved for home training should retain oversight responsibility for the patient and the caregiver as per current home training/home dialysis standards, regardless of whether the caregiver is a paid employee of the training facility, the institution, the patient, or a DME company. We believe that, in recognition of the fact that these patients may have limited skills and abilities, the requirement to train the patient should be waived. Likewise, in recognition of the limited space in such institutional settings, the requirement for one dialysis machine per patient should be waived, and we do not believe that would equate to the creation of a dialysis facility. ANNA does not believe that such institutions should be required to meet these Conditions for Coverage just because they house home dialysis patients. Financial practicalities preclude requiring a nurse to perform all dialysis treatments in these settings, although at times that will be the case. We recommend that a standard be developed based on input from the renal care community that would address the decision-making as to patient-level characteristics that affect the type of caregiver required. ANNA believes that experienced dialysis clinicians (and the experience should be defined) should be able to dialyze multiple patients in the same room, depending on the patients' acuity and stability, as long as personnel from the institution are available to help provide routine medical tasks unrelated to dialysis, like taking vital signs, if and when needed.

These are our initial thoughts on this subject and, as mentioned, we look forward to continuing our dialogue with the Agency on this important subject before a Final Rule is promulgated.

## **QAPI**

**§494.110(a)(1):** ANNA agrees with the inclusion of a condition requiring a "Quality Assessment and Performance Improvement" program to demonstrate commitment to improved health outcomes and prevent and reduce medical errors.

**§494.110(a)(2):** ANNA agrees with all items listed in the rule for performance components but requests the addition of "bone disease management" as well as "infection."

**§494.110(a)(2)(vii):** With regard to the use of a common instrument for assessing patients' experience of care, ANNA believes this makes a lot of sense and should pose only a minimal time burden for the facilities. However, such paperless technology could initially be expensive and we do not believe it is reasonable to expect that facilities could afford it.

Regarding how facilities will “assess the effectiveness of their internal grievance adjudication process, track the outcomes of patient grievances, and identify meaningful criteria for evaluation and tracking purposes,” ANNA suggests there should be a standardized tool for patient satisfaction and grievance reporting. It could be brief and concise, and facility specific questions could be added to the standardized tool for internal use. Please note that we believe this patient satisfaction tool should be administered routinely, not just in response to a grievance. Prevention of grievances should be the goal.

**§494.110(c):** ANNA applauds the requirement for prioritizing improvement activities and having a plan for immediate correction of identified problems that jeopardize patients’ health and/or safety.

### **Special Purpose Renal Dialysis Facilities**

**§494.120:** ANNA believes that if the camp is doing dialysis on site, the facility should also meet the requirements for qualified personnel as in the rule §494.150 (a) Medical Director (b) Nursing Services (e) Patient Care Technicians, and (f) water treatment system technicians.

**§494.120(d):** ANNA agrees that the rule for physician contact is ideal but during natural disasters such as hurricanes, it may be impossible to contact the patient’s attending physician. There should be a provision for another physician to provide direction of care in such extenuating circumstances.

### **Personnel Qualifications**

ANNA agrees with the preamble statements about dialysis technicians, but believes it is more appropriate to say they are the **predominant** direct patient caregivers in most dialysis facilities. The recognition that they function as extensions of the facility’s professional nursing staff is also very helpful.

ANNA further agrees with CMS that it is essential that a registered nurse provide the “hands-on” direct supervision to technicians during the clinical component of their training, provided direct supervision is defined as we have suggested in the definitions comments at §494.10. Facilities would not have the staff to permit RNs to provide immediate supervision of these technician trainees. Please refer to our distinction between these definitions at §494.10.

ANNA does not believe there is a need for clinical pharmaceutical services beyond continuing staff education on new products for both incenter and home dialysis patients. RNs are the appropriate professionals to monitor patients’ medications and do patient teaching. We believe it could be confusing to the patient to further fragment care by introducing another discipline into the patient care scenario. RN workloads could be reduced and patient care improved with regard to medication management by the use of technology for dose conversion, verification, labeling, documentation, and checking for drug-drug interactions. ANNA looks forward to working with CMS, networks or others in the renal community in this regard.

ANNA looks forward to reimbursement methodologies that incorporate pay for performance and that promote the use of disease management models. In those scenarios, Advance Practice Nurses will more likely be employed to function as case managers and we believe patient care and outcomes will improve and hospitalizations will decrease.

**§494.140(b)(3)(i):** ANNA strongly opposes the language allowing LPN/LVNs to function as charge nurses. The role of a charge nurse is to supervise and direct the clinical activity while patients are dialyzing at a facility. Most states define the role of licensed practical/vocational nurses along these lines: "the provision of care, *under the supervision of* a physician practicing medicine, or a registered nurse practicing nursing in accordance with applicable provisions of law." In no state in the United States can an LPN/LVN supervise an RN, and these proposed conditions require the presence of an RN when patients are dialyzing. Given this reality, the conditions cannot permit LPN/LVNs to be charge nurses.

### **Medical Records**

ANNA appreciates the elimination of the requirement for a medical records supervisor.

**§494.170(d):** ANNA believes that requiring all medical records be sent within one working day of a patient's transfer is unrealistic and unnecessary. We believe that only those records that a medical care provider and the facility require to adequately assess and treat the patient safely are necessary upon transfer. Those would include at least the current care plan, one month of treatment records, current physician orders, and medication list. Some patients have received dialysis treatment in a single center for many years, and requiring the entire medical record is unreasonable and burdensome in these circumstances.

### **Governance**

**§494.180(b)(1):** ANNA wholeheartedly endorses the inclusion of a requirement for an acuity-based staffing plan to ensure that every dialysis facility has "adequate and appropriate staffing" to meet the needs of its patients. The utilization of an acuity based system to determine the adequacy and appropriateness of the numbers and skill mix of staff required to deliver care would provide for improved quality of care. Literature describing acuity-based staffing indicates outcomes of improved quality of care and the reduction of staff burnout, resulting in lower rates of staff absenteeism and turnover.

With regard to the concern about "cherry picking" as a result of using minimum standards for accountability purposes, ANNA believes this risk could be minimized by the adoption of a true patient-level acuity-based reimbursement system including an acuity-based staffing model. This would encourage facilities to accept and properly care for patients who are more resource intensive or more difficult to manage and who are less likely to achieve acceptable levels on the performance measures. In the past ANNA developed the basis for a staffing-acuity model; we would welcome the opportunity to collaborate with CMS to update and refine this model to meet the intent of this proposed rule.

**§494.180(b)(2):** ANNA strongly supports this proposed requirement. Dialysis patients are, after all, receiving *nursing* care for the duration of their stay in the dialysis facility such that a registered nurse must be present. This is a long overdue requirement and we are most pleased to see it. It must remain in the final rule.

**§494.180(b)(5)(i) through (viii):** ANNA agrees that the patient care technician training program should incorporate, at a minimum, these content areas, and most already do. **ANNA strongly recommends a requirement that all patient care technicians should be certified through a nationally recognized certification program.** Successful completion of a standardized certification exam would validate the success of the training program and would provide assurance to the public and to patients that all patient care technicians have a certain minimal level of preparation. While there are currently three national certification exams available for dialysis technicians, only one is designed to test at the competency level. The other two exams are higher levels and may be difficult for the entry-level technician. The competency level exam is the Certified Clinical Hemodialysis Technician (CCHT) offered by the Nephrology Nursing Certification Commission (NNCC) in cooperation with the Center for Nursing Education and Testing (C-NET). More information can be obtained about this examination at the NNCC website, [www.nncc-exam.org](http://www.nncc-exam.org). We agree that the skills and competencies of patient care technicians are a major patient concern and applaud these steps to mandate a standard minimum program. **We urge CMS to take the additional step to require validation of minimal competency by requiring certification of patient care technicians.**

**§494.180(c):** ANNA agrees with CMS on the proposal to delete process requirements for medical staff appointments and add a new governing body requirement to inform the facility's medical staff regarding the facility's patient care policies and the facility's QAPI Program.


**§494.180(f)(4):** ANNA supports and appreciates the guidance provided for involuntary discharge of a patient. We further support the statement about facility accountability for personnel adherence to the patient discharge or transfer policies and procedures.

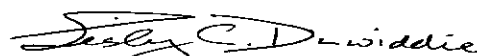
**§494.180(g)(3):** ANNA thinks it is reasonable to remove the requirement for an affiliation agreement with an ESRD certified hospital and the substitution of an agreement with a (any) hospital that can provide inpatient care.

**§494.180(h):** ANNA believes that whatever can be done to reduce the burden of information collection by automated systems, universal data collection tools, and quarterly collections, would certainly reduce the burden for registered nurses to whom such data collection is frequently assigned.

ANNA wishes to thank CMS for the opportunity to review and provide comment on these proposed Conditions for Coverage. The order of the content and the references to the existing regulations along with the proposed changes enabled us to understand and reflect on the benefits of the proposed changes. We are impressed with the patient focus of the proposed conditions and believe that the final rule, incorporating our suggested amendments, will lead to greater facility flexibility to focus on improving patient outcomes.

Very truly yours,

  
Suzann VanBuskirk, BSN, RN, CNN  
President 2005-06

  
Lesley Dinwiddie, MSN, RN, FNP, CNN  
President 2004-05

cc: ANNA Board of Directors



58

INNOVATIVE DIALYSIS  
S Y S T E M S ■ I N C.

April 29, 2005

Dr. Mark McClellan, Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3818-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

RE: CMS-3818-P: Conditions for Coverage for End Stage Renal Disease Facilities

Dear Dr. McClellan:

Innovative Dialysis Systems, Inc. welcomes the opportunity to comment on the Proposed Conditions for Coverage for ESRD facilities. We support the shift from the process to the outcome domain and support improved patient care in outpatient dialysis. We would like to emphasize however, that changes in regulatory requirements should be carefully considered to ensure that they are cost-effective and do not place undue economic burden on the provider community, especially those with unproven beneficial impact on patient care.

Please find our comments attached.

Sincerely,

Karen B. Dyer  
Risk Manager/ Corporate Compliance Officer

## CMS-3818-P

Comments on the proposed changes in the Conditions for Coverage for ESRD Facilities.

### **Water Quality:** (Proposed § 494.40)

#### *Chlorine/chloramines (Proposed § 494.4(c) (2) (ii) (A))*

If the test results are greater than 0.10 mg/L for chloramines as specified in paragraph (c)(2)(i), immediate termination of dialysis need not be the only alternative to protect patients. Some facilities use the addition of ascorbic acid to their acid concentrate to accommodate the removal of chlorine/chloramines from the water should the primary and secondary carbon tanks become exhausted.

We recommend a change in regulatory wording to state: Immediately terminate dialysis treatment to protect patients from exposure to chlorine/chloramines, **OR**, for facilities that add ascorbic acid to their acid concentrates, should there be breakthrough exceeding the limit of 0.1 mg/L of chlorine or chloramine at the secondary carbon tanks, the ascorbic acid policy having been implemented, the dialysate from each acid bath in use should be tested for the concentration of chlorine/chloramines. If the level of this test exceeds the limit of 0.1 mg/L then immediately terminate dialysis treatment.

### **Patient Safety** (Proposed §494.30)

#### *Infection Control (Proposed §494.30(b)(2))*

The standard for oversight would designate a Registered Nurse as the infection control or safety officer for the ESRD facility. Under current Conditions, this is the responsibility of the Medical Director. In the proposed conditions, the Medical Director "is responsible for the delivery of patient care and patient outcomes in the facility." Additionally, the current Conditions require that the Medical Director ensure that staff in the unit are adequately trained and ensure the development of patient care policies and procedures and these responsibilities would be carried over in the new Conditions. Finally, in the new conditions the facility's QAPI program would be the operational responsibility of the Medical Director. Since the Medical Director maintains responsibility in all of the areas that impact infection control, we believe the tracking and trending of infections should remain a function of the QAPI process, under the direction of the Medical Director.

### **Physical Environment** (Proposed §494.60)

#### *Emergency Equipment and Plans (Proposed §494.60(d)(3))*

You have requested comment regarding small rural ESRD facilities and the potential for an exemption from the requirement for an AED or other defibrillator. Under the assumption that a small rural facility is potentially some distance from emergency medical care and under the circumstance that every airport and commercial aircraft in this country as well as many retail stores have AED access, it seems inconceivable that a healthcare facility would not. We believe that there should be no exemption from the delivery of safe care.

### **Patients' Rights** (Proposed §494.70(a)(2))

"Receive all information in a way that he or she can understand"

While we are all sensitive to the importance of providing information to patients, to mandate that the dialysis unit provide *all information*, regardless of language barriers, is,

in our opinion, a situation destined for failure, even if the mechanism for providing the information is left to the dialysis unit. We would like to suggest regulatory language change such as:

"To have the dialysis facility make a clear and documented effort to assure that every patient receives all information in a way that he or she can understand."

*Advance Directives (Proposed §494.70(a)(5))*

Thank you for including the patient's right to complete an advance healthcare directive in the proposed new set of patients' rights. It was unfortunate that the ESRD community was not included in the 1990 Patient Self-Determination Act and will be in the best interest of our patients to have that oversight corrected. We would like to suggest that the standard be carried one step farther and state that an ESRD facility must honor the directive presented by any patient for whom it was important enough to prepare a directive. If an ESRD facility is unable or unwilling to honor a directive, that facility should be required to notify the patient and assist the patient in a timely transfer to a facility that is willing to honor the directive.

**Patient Assessment (Proposed §494.80)**

The NPRM states "the interdisciplinary team consisting of, at a minimum, the patient (if the patient chooses) or the patient's designee..." (70 Fed. Reg. at 6203). Although we agree that it is in the best interest of the patient to take an active role in his/her care plan, not all dialysis patients choose for themselves or a designee to participate in the care planning process. We recommend the following change in regulatory language: "*the patient or his/her designee (if he or she chooses)...*"

We also recommend that a nurse practitioner or physician assistant working under the supervision of a nephrologist be able to complete the physician portion of the assessment.

*Patient reassessment (Proposed §494.80 (d)(2))*

You have solicited comment regarding the implementation of a second assessment performed on new patients at the interval of three months. The intent of this section appears to be to allow a patient to stabilize so that a revision may be made in the patient's plan of care. Depending upon the acuity of the patient's condition on admission, three months might not be sufficient time for the patient to stabilize on maintenance dialysis. We would like to suggest that the second assessment of the new patient be performed at a six month interval following admission to the facility in order to assure that an effective plan of care might be formulated.

*Patient Reassessment (Proposed §494.80 (d)(2)(i-iv))* The definition for "unstable" is vague. We are uncomfortable with terms like "extended" or "frequent" or "marked" or "significant." If the expectation is that the facility will define these, then perhaps the regulations need to so state. We would like to suggest that CMS consider that each facility must have a written definition of "unstable patient," approved by the Medical Director and using community guidelines.



#### **Plan of Care (Proposed §494.90)**

##### *Development of the Plan of Care (Proposed §494.90(a))*

You have solicited comment on the possible use of and appropriate minimum threshold for values for the adequacy of dialysis. The NKF-K/DOQI adequacy levels for Kt/V and URR are reasonable and achievable for the majority of dialysis patients. However, regulatory language should allow for flexibility in the individualized care of patients, while providing structure for the whole. The critical role that patients play in outcomes is not addressed in the regulations and we urge that it clearly be stated that documentation/justification of the failure to comply with the treatment regimen be allowed as reason for the failure to meet criteria within the plan of care.

##### *Development of the Plan of Care, Rehabilitation (Proposed §494.90(a)(6))*

Rehabilitation is recognized as an important aspect of quality patient care. The role of the dialysis facility in the actual provision of rehabilitative-specific care beyond education, support and encouragement is limited.

The NPRM states that "the interdisciplinary team must provide the necessary care and services for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of the pediatric patient..."

While this would be ideal, limitations are acknowledged in the preamble, stating that the facility will not be held accountable for rehabilitation outcomes that are beyond the facility's control.

We suggest the wording be changed in the final regulations to the following, "*the interdisciplinary team must assist the patient in achieving the level of productive activity he/she desires by providing encouragement, educational materials, social worker support and referrals to community services.*"

##### *Implementation of Patient Plan of Care (Proposed §494.90(b)(4))*

We believe that the quality of patient care and the level of patient satisfaction are both improved by regular physician-patient visits. However, the proposed rule would hold dialysis facilities responsible for the activities of providers, i.e. physicians, over whom the dialysis facility has no control. We recommend the elimination of the requirement that the dialysis facility is responsible for the physician seeing the patient in the dialysis facility.

##### *Implementation of Patient Plan of Care (Proposed §494.90(c))*

We question the benefit of duplicating transplant referral tracking already required of transplant centers. There is value in documenting in the patient record that patient's transplant status as determined by a transplant center. Transplant centers are required to notify the dialysis facility of a patient's transplant status following referral through their own Conditions of Participation. 70 Fed. Reg. at 6161 (§482.94(c)). When a patient's status changes, the transplant center should contact the dialysis facility so that it can update the patient's records. We recommend the regulatory language be changed to reflect that the patient care team maintain a list of patients on the active transplant waiting list, as provided by the transplant center.

**Care at Home (Proposed §494.100)**

*Care at Home, Support Services (Proposed §494.100 (c))*

Mandating visits to the home of patients on home hemodialysis and home peritoneal dialysis should be treated differently. Home visits to patients receiving home peritoneal dialysis should be required only when medically indicated. In the absence of a need for water treatment there is not the medical necessity for home visits for peritoneal dialysis patients as there is for home hemodialysis patients. The regulation proposes to retain the existing requirements regarding periodic surveillance of the patient's home adaptation. Routine visits to the home of patients on Continuous Ambulatory Peritoneal Dialysis (CAPD) are unnecessary as there is no equipment needed and exchanges can be done in any clean area. Visits should be as needed, e.g. frequent infections.

Routine visits for Continuous Cycling Peritoneal Dialysis (CCPD) home patients should also be done as needed since there is no water treatment required and machine disinfection and repairs to equipment are typically provided by the manufacturers' personnel. Visits should be required on the same basis as CAPD patients, only as needed for frequent infections. We recommend the language be changed to read: "*....conduct periodic monitoring of the patient's home adaptation, including home visits to the home for home hemodialysis patients and visits to home peritoneal dialysis patients if medically necessary...*"

**Personnel Qualifications (Proposed §494.140)**

*Social Worker (Proposed §494.140(d))*

We would like to propose that the definition of a qualified social worker be an individual who "Holds a master's degree in social work from a school of social work accredited by the Council on Social Work Education." We suggest deletion of section (2) regarding "meeting the requirements for social work practice in the state in which he or she is employed." Some states have been reticent to define the qualifications that would cause a social worker to meet their definition of "qualified." This has resulted in inconsistency in state surveys. Since there is a national definition of "Social Worker" as established by the Council on Social Work Education, and since CMS has determined that definition to adequately describe a professional who can provide social services in the ESRD community, we recommend deletion of the state involvement in defining social work qualifications.

*Patient Care Dialysis Technicians (Proposed §494.140(e)(3))*

The requirement that patient care technicians receive three months experience "under the direct supervision of a registered nurse" following the facility's training program needs clarification. Typically an RN is responsible for the oversight and training of all new patient care staff, but may have assistance from a preceptor who shares the same role as the new trainee. It is unrealistic to require that an RN be the only experienced personnel directly involved in the training of patient care technicians for a three-month period. We recommend revising the language to remove the word "direct" and state "*This experience must be under the supervision of a registered nurse*".

May 2, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3818-P  
PO Box 8012  
Baltimore, MD 21244-8012

Re: Medicare Program, Conditions for Coverage for End Stage Renal Disease Facilities  
Proposed Rule  
494.140d

To Whom It May Concern:

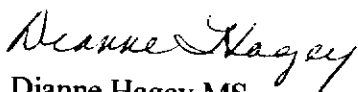
This comment is to request a reconsideration of the requirement for a masters of social work for the dialysis setting. Please know that I am in total agreement with the need for a masters prepared individual to be employed to assist on an ongoing basis with the needs of the renal patient. I believe this position however can be more than adequately filled by someone who has obtained a masters degree in a related field such as counseling with an emphasis in family dynamics. I am proposing that the requirements for the position of social worker be filled by a masters of social work or a masters in a related field. Yes, there would be some differences in the curriculum requirements or field placements but I believe there have also been some differences in the curriculum for a master of social work over the last forty years.

At the very least I would like to suggest that there be put in a place an appeal process so that an individual with a masters in a related field to social work who demonstrates no deficiencies in the dialysis setting should be exempted from the masters in social work requirement. I am aware this exemption has been allowed in the past.

The goal of the ESRD program has always been to assist the patient reach the highest quality of life possible. An individual with a masters degree in counseling certainly has the skills and qualifications to help a patient obtain this goal.

Thank you for your consideration.

Sincerely,



Dianne Hagey, MS  
5708 Glen Vale Drive  
Knoxville, Tennessee 37919

56

# NKF National Kidney Foundation®

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A. BRUCE BOWDEN, Esq.

May 2, 2005

Hon. Mark B. McClellan, MD, Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3818-P  
PO Box 8012  
Baltimore, MD 21244-8012

Dear Dr. Mc McClellan:

I am pleased to submit comments on the Proposed Rule, "Medicare Program: Conditions for Coverage for End Stage Renal Disease Facilities," CMS-3818-P, that was published in the *Federal Register* on February 4, 2005. This response is being filed on behalf of the 50,000 members of the six constituent councils of the National Kidney Foundation (NKF):

Patient and Family Council  
transAction Council (serving the interests of transplant candidates and recipients)  
Donor Family Council  
Council on Renal Nutrition  
Council of Nephrology Social Workers  
Council of Nephrology Nurses and Technicians

We will address the issues in the order that they appear in the preamble to the Proposed Rule.

## Basis and Scope

NKF strongly endorses the patient focus and the emphasis on patient outcomes that constitute the core principles of the Proposed Rule. In particular, we appreciate the agency's concern that patients receive the type of kidney replacement therapy that is most appropriate for them. Nonetheless, patient assessment and education for modality selection should occur before the initiative of dialysis when options are meaningful rather than after they are already under the care of a hemodialysis clinic. Indeed this is one of the objectives of the Department's "Healthy People 2010" project to increase the proportion of treated chronic kidney failure patients who have received counseling in nutrition, treatment choices and cardiovascular care 12 months before the start of renal replacement therapy. (Objective 4-30)

The Interpretive Guidelines that will be developed to assist state survey agencies in evaluating compliance with the Final Rule should have a corresponding thrust. Therefore, NKF recommends that CMS constitute an advisory body, with broad representation of dialysis providers, nephrology health care professionals, and kidney patients, to review the Interpretive Guidelines as they are being developed to make sure that they are consistent with the spirit expressed in the preamble of the Proposed Rule.

**Definitions (Proposed Section 494.10)**

Dialysis provided in a nursing facility or skilled nursing facility should not be considered to be self care home dialysis. It is more accurate to characterize it as staff-assisted home dialysis.

**Compliance with Laws and Regulations (Proposed Section 494.20)**

We are concerned about the application of the requirement regarding drug and medical device usage. While we agree that dialysis facilities should adhere to the labeling instructions for medical devices, they should not be found to be in violation of the conditions of coverage in the case of off-label use of pharmaceuticals. The Food and Drug Administration recognizes off-label use of drugs and a physician may determine that his/her patient would benefit from the administration of a drug for an indication that is not specified in that drug's package insert. Therefore, the Final Rule should make it clear that the requirement for adherence to labeling instructions does not apply to pharmaceuticals.

NKF recommends that CMS reference the Americans with Disabilities Act in this section in the Final Rule.

**Infection Control (Proposed Section 494.30)**

The Final Rule should be consistent with CDC recommendations for testing dialysis patients for hepatitis C. In addition, every new dialysis patient should have testing done for hepatitis C and its antibody at initiation of chronic dialysis.

**Water Quality (Proposed Section 494.40)**

The Proposed Rule requests comments on the need for a requirement for ultrapure dialysate. No one has advocated sterile dialysate. While there is some indication in the literature that ultrapure dialysate could have a positive impact on morbidity and mortality, only small studies have been conducted and there have been no prospective, randomized trials. Therefore, NKF recommends that AAMI evaluate the need for ultrapure dialysate and that, pending such an evaluation, including such a requirement in the Final Rule would be premature.

Comments are also requested with regard to frequency of water purity testing. Because of the variation between dialysis facilities with respect to length, number, and scheduling of shifts, the Final Rule should specify that water should be tested at the beginning of the day and every four hours while patients are being dialyzed.

NKF supports a requirement for a backup system for reverse osmosis equipment.

**Physical Environment** (Proposed Section 494.60)

NKF supports the requirement for defibrillators in all dialysis clinics, even small ones that serve patients in predominantly rural areas. The cost is minimal. Therefore there is no reason to permit exceptions. The Final Rule should require facilities to be accessible to people with disabilities, as required by the Americans with Disabilities Act. It should also require facilities to have a place for confidential interviews with patients and families and to provide for privacy during body exposure. Such a requirement would be consistent with the Health Insurance Portability and Accountability Act.

**Patient Rights** (Proposed Section 490.70)

NKF supports the requirement, in proposed section 494.70(a) (5), that patients be informed about the right to establish an advance directive. In the past we have advocated that the advance directive requirement in the Omnibus Budget Reconciliation Act (OBRA) of 1990 be extended to encompass dialysis facilities. OBRA requires that hospitals, skilled nursing facilities, home health agencies, managed care plans, and hospice programs participating in the Medicare program must establish and maintain written policies and procedures regarding advance directives.

NKF recommends that proposed section 494.70 (a) (6) be amended. Not only should dialysis patients be informed about all treatment alternatives, but, if the provider does not offer a particular modality, patients should be informed about how to locate a facility that offers that service.

NKF recommends that proposed section 494.70 (10) be amended. The draft provision indicates that the patient has the right to be informed of services available in the facility. This should be expanded to specifically mention social work services, psychosocial counseling, and nutritional counseling.

A new subsection should be added to proposed section 494.70(a), to inform patients about the right to schedule treatments to accommodate work or school.

Finally, proposed section 494.70(b), relating to a patient's right to be informed about the facility's discharge and transfer policies, should reflect the intent in the preamble to the Proposed Rule, that

noncompliant behavior should not be the basis for involuntary discharge. This would reduce incentives to “cherry pick” patients to improve performance measures.

With regard to proposed section 494.70 (c), “Posting of Rights,” facilities with patients who are unable to read the patients’ rights poster must have an alternate way to inform those patients of their rights.

**Patient Assessment (Proposed Section 494.80)**

NKF supports the statement in the preamble to the Proposed Rule that every patient assessment should focus not only on the patient’s medical needs, but also on his or her psychosocial and rehabilitation needs. Along that line, the description of the interdisciplinary team in section 494.80 should make it clear that a *qualified* social worker must be part of the team. Moreover, assessment should include the use of the SF-36 or other standardized survey that permits reporting of, or conversion to, a physical component summary (PCS) score, and mental component summary (MCS) score, and all domains of functioning and well-being measured by said survey. The literature supports the value of the PCS and MCS scores to predict morbidity and mortality of ESRD patients and to indicate the need for intervention.

The description of the health care team should specify that the dietitian must be a *registered* dietitian.

Proposed sections 494.80 (6) (“Evaluation of nutritional status”) and 494.80(7) (“Evaluation of psychosocial needs”) requires additional specificity so that there is consistency in assessment across the nation.

Proposed section 494.80 (9) (“Evaluation of patient’s...level of participation in the dialysis care process”) should include assessment of the patient’s potential for self-cannulation. If the patient chooses not to participate in the dialysis care process, the basis for nonparticipation should be documented in the medical record. Similarly, if the patient is not a candidate for referral for home dialysis, the basis for nonreferral should be documented in the medical record.

**Because of the extent and severity of cardiovascular disease in the dialysis population, we suggest an additional component be added to the patient assessment section in the Final Rule, namely, cardiovascular health.** At the initiation of dialysis, all patients should be assessed for cardiovascular disease (CAD, cardiomyopathy, vascular heart disease, CBVD, and PVD), as well as screened for both traditional and non-traditional cardiovascular risk factors.

Instead of the Proposed Rule’s requirement that comprehensive assessment of new patients be completed within 20 days and that a patient care plan be implemented within 10 days after that assessment is completed, NKF recommends that the Final Rule allow 30 days for both assessment

and implementation of patient care plan. A 30 day window will facilitate participation by all members of the health care team in this process. Furthermore, the Final Rule should specify how this time frame will be calculated. Since the first dialysis treatment often occurs during an inpatient stay, the clock should not begin to run until the first outpatient dialysis session. In addition, if a new dialysis consumer changes providers, patient assessment and the patient care plan should be completed within 30 days after permanent placement.

NKF endorses the proposal for a comprehensive re-assessment of new patients within three months since the medical condition of new patients is often unstable during that period, changes in access to third party payment take place after 90 days, vascular access planning may require follow-up, and because there is evidence from the "Right Start" program that intensive care in the first six months of dialysis appears to reduce morbidity.

NKF endorses monthly re-assessment of unstable dialysis patients. On the other hand, the definition of unstable patient requires more specificity than is found in the Proposed Rule. For example, terms like "marked" are not operational. "Significant" could be substituted. The NKF CNSW recommends these additional criteria for monthly reassessment: (v) reduced physical component summary (PCS) score on a validated measure of functioning and well-being, and (vi) reduced mental component summary score on a validated measure of functioning and well-being.

#### **Plan of Care (Proposed Section 494.90)**

The Final Rule should retain the requirement that a transplant surgeon or his/her designee (e.g. a transplant coordinator) be included in the interdisciplinary health care team.

#### Dose of Dialysis

NKF recommends that the following language be added to proposed section 494.90(a)(1): "The dose of dialysis should allow the patient to achieve current community-accepted standards for dialysis adequacy, i.e. the patient plan of care should specify a minimum delivered threshold for Kt/V of at least 1.2 (single pool) for hemodialysis patients; 1.7 (weekly) for peritoneal dialysis patients; 2.1 (weekly) for continuous cycling peritoneal dialysis patients; and 2.2 (quarterly) for intermittent peritoneal dialysis patients. Additionally, the provision requiring periodic measurement to assess the adequacy of the patient's dialysis prescription should be moved from proposed section 494.80(c) to this section.

#### Nutritional Status

In addition to monthly measurement of albumin, a nutritional outcome measure that evaluates weight, i.e. body mass index, may also be beneficial.



Anemia

The NKF Kidney Disease Outcomes Quality Initiative (K/DOQI) will publish new guidelines for the management of anemia in chronic kidney disease during the first quarter of 2006. The multidisciplinary team should consider these recommendations in developing patient care plans.

Vascular Access

NKF recommends that vascular access monitoring should include physical examination by a qualified team member at least monthly, to detect dysfunction in A-V fistulae and grafts. Persistent abnormalities should prompt referral for access angiography.

Transplantation Status

The interdisciplinary team can assist in assessing whether a dialysis patient should be a candidate for transplantation and facilitating the evaluation process once the patient has been referred for transplantation. On the other hand, it is the nephrologist who has the responsibility for referral to a transplant center. The suggestion in the preamble to the Proposed Rule that dialysis facilities refer patients for transplantation should be corrected.

Transplantation Referral Tracking

The interdisciplinary team should maintain a communications link with the transplant center after a patient has been referred for transplantation. However it is the transplant center that has the prime responsibility for communications about a candidate's transplant status. Furthermore, the Proposed Rule for transplant centers, CMS-3835-P, should address the frequency of those communications.

Social Services

Researchers have found that psychosocial issues negatively impact health outcomes of patients. Conversely, social work interventions contribute to the achievement of the patient outcomes that the patient care team is striving to attain. Studies have shown that social work intervention improves adherence to the ESRD treatment regime and fluid restriction, as well as medication compliance. Social work interventions can reduce patients' blood pressure. With regard to psychosocial outcomes, social work counseling can reduce patients' anxiety levels. Physical component summary (PCS) scores and mental component summary (MCS) scores can be improved through social work interventions. Finally, several researchers have determined that nephrology social work counseling significantly improves quality of life for ESRD patients.

**NKF recommends that the patient plan of care address two additional areas:  
Cardiovascular Health, and Management of Bone and Mineral Metabolism.**

Cardiovascular Health

NKF recommends that electrocardiograms be performed in all patients at the initiation of dialysis, once patients have achieved dry weight and at 2-yearly intervals thereafter. Appropriate blood pressure management is an important part of dialysis care and contributes directly to cardiovascular health. Please see National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Cardiovascular Disease in Dialysis Patients. Am J Kidney Dis 45:S1-S154, 2005 (suppl 3)

Management of Bone and Mineral Metabolism

NKF recommends that serum phosphorous and serum calcium concentration be measured at least monthly. Serum parathyroid hormone (PTH) concentration should be measured at least every three months or more frequently, if needed to monitor response to vitamin D therapy. Please see: National Kidney Foundation K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. Am J Kidney Dis 42:S1-S202, 2003 (suppl 3).

Implementation of the Patient Care Plan (Proposed Section 494.90(b))

CMS solicited comments regarding whether physicians should be required to see their in-center patients periodically while those patients are being dialyzed in the dialysis facility. NKF believes that such a requirement would advance the goal of multidisciplinary care by providing the nephrologist the opportunity to interact with dialysis staff. On the other hand, it is not possible to conduct a complete physical examination when a patient is in a dialysis chair.

Patient Education and Training (Proposed Section 494.90 (d))

The National Kidney Foundation is committed to ongoing education for patients and family members or caregivers through the various stages of kidney disease. They need to be empowered so that they can contribute to achieving treatment goals and play an active role in the dialysis health care team. On the other hand, for maximum effectiveness, patient education should be provided before kidney replacement therapy is initiated. That is the appropriate point in time for modality selection, and vascular access choice, and to prepare the patient and family members for the requirements of life on dialysis. That is why the National Kidney Foundation supports the creation of a Medicare education benefit for patients in Stage 4 of chronic kidney disease, as proposed in S. 717, the Kidney Disease Educational Benefits Act of 2005 , and in Section 302 of the Kidney Care Quality and Improvement Act of 2005 (S. 635 and H. R. 1298).

### **Care at Home**

While the proposed requirements for the oversight of the care received by home dialysis patients would provide a new level of patient protection, they will make traditional home dialysis more expensive to provide and could serve as a deterrent to referral for home dialysis. The Final Rule should recognize the fact that it is not necessary to monitor water quality or dialyzer reuse with certain new home dialysis technologies. Monthly reporting of supply usage is too burdensome.

The proposed division of responsibility (for care of institutionalized dialysis patients) between dialysis facilities and nursing homes is not practical. Nursing homes don't have the staff or financial resources to provide the level of services specified in the Proposed Rule and will either refuse to accept patients being discharged from hospitals or fall short in meeting their responsibilities. There is constant turnover in nursing home staff and there would be a continuous need for dialysis facilities to train new nursing home staff in the care of ESRD patients if the model described in the Proposed Rule is adopted. If a nursing facility or skilled nursing facility provides full-scale dialysis to residents with ESRD, it must become certified as a dialysis facility and comply with all Medicare conditions, including personnel qualifications. Alternatively, dialysis services delivered in a nursing home or skilled nursing facility should be provided by a satellite of an existing dialysis provider.

### **QAPI (Proposal Section 494.110)**

#### Scope of Quality Assessment and Performance Improvement Program

In addition to the seven items listed in proposed section 494.110 (a) (2), NKF recommends that dialysis facilities be required to analyze and track quality indicators or other aspects of performance that relate to: (viii) cardiovascular health, (ix) management of bone and mineral metabolism, (x) mental health and (xi) patient functioning and well-being. Moreover the Final Rule should state that, in developing a quality assessment and performance program, the dialysis facility should take into consideration current evidence-based community-accepted clinical practice guidelines, such as those developed under the NKF Kidney Disease Outcomes Quality Initiative (K/DOQI). CMS invited comment on the value of utilizing one common survey instrument to assess patient satisfaction that can yield information permitting comparisons of facilities across the nation. We believe that it would be appropriate for CMS to provide core questions for such a survey instrument, but that dialysis providers should be allowed to add additional questions to address local issues and concerns.

#### Facility-Wide Standards of Enforcement

We have concerns about using the K/DOQI clinical practice guidelines to develop quality

assurance requirements or enforceable facility-wide performance standards. Whether or not a specific dialysis clinic is able to meet K/DOQI goals for the bulk of its patients could be affected by case mix, patient compliance, and biologic variability, or any combination thereof. Another variable is patient access to third party payment for services not covered by Medicare. Moreover, if a seemingly unacceptable number of patients in a particular facility are outliers, it would be impossible to collect the information that is needed to determine whether there's justification for the failure to achieve K/DOQI goals. Finally, guideline development is a dynamic process, driven by scientific developments. For example, NKF is currently completing the second revision of the guidelines initially published in 1997 for hemodialysis and peritoneal dialysis adequacy, and vascular access, and a completely new guideline for anemia management in chronic kidney disease. The regulatory process does not afford the flexibility to keep pace with clinical practice guideline development.

## **Personnel Qualifications (Proposed Section 494.140)**

This section should be expanded to include Responsibilities as well as Qualifications. Alternatively, the Final Rule should contain a new section, specifying the responsibilities of nursing staff, dietitians, and social workers, similar to Proposed Section 494.150 detailing the responsibilities of the medical director. For example, the conditions of coverage should specify the responsibilities of a qualified social worker so that practice settings are not assigning inappropriate tasks and responsibilities to social workers. Tasks that are clerical in nature or involve admissions, billing, and determining insurance coverage prohibit nephrology social workers from performing the clinical responsibilities that are central to their mission.

### Medical Director

NKF recommends that the Final Rule should retain the requirement that the Medical Director of a dialysis clinic be Board certified or Board eligible.

### Dietitian

The updated qualification requirements for the renal dietitian are appropriate to allow for an advanced scope of practice. The requirement for 1 year of professional work experience in clinical nutrition as a registered dietitian is acceptable, but 2 years of professional work experience would be ideal. Also, for a newly hired renal dietitian without renal experience there should be a training period of at least two weeks under an experienced renal dietitian.

The Final Rule should include the following responsibilities of dietetic staff:

5. monitoring adherence and response to diets;
6. recommending interventions for improving nutritional status.

7. The dietitian may also be designated as anemia, bone or urea kinetic modeling manager to improve patient outcomes.

Laboratory indices reflecting nutritional status of kidney patients are also affected by the co-morbid conditions of anemia, cardiovascular disease and secondary hyperparathyroidism. Since some of these indices are also recognized to be predictive of patient outcomes, the renal dietitians' clinical role has been expanded to a more advanced level of clinical care that involves monitoring interventions for these co-morbid conditions as well as for overall nutritional health.

#### Social Worker

The chronicity of End Stage Renal Disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping to chronic illness, concern about mortality & morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle changes, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational) dependency issues, and diminished quality of life. The gravity of these psychosocial factors necessitate an assessment and interventions conducted by a qualified social worker.

The ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential.

The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which he or she is employed; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including patients' social, psychological, cultural and environmental barriers to coping to ESRD and their treatment regime; provide patients and their support networks emotional support, encouragement and supportive counseling; provide assistance with adjustment and coping to ESRD, comorbidities and treatment regimes, including treating patient depression; patient and family education; assist with psychosocial barriers to transplantation and home dialysis; crisis intervention; assistance with advance directives and self-determination issues; assisting patients with obtaining maximum rehabilitative status (including: ongoing assessment of barriers to patient goals of rehabilitation; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); provide staff in-service

education regarding ESRD psychosocial issues; participate in the facility's quality assurance program; mediate conflicts between patients, families and staff; participate in interdisciplinary care planning and collaboration, and patient advocacy.

Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. Social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. Changing the language of this definition to include a specialization in clinical practice will conform it to the definition of a qualified social worker in the Conditions of Participation for transplant centers, CMS-3835-P. NKF supports the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. The master in social work degree (MSW) provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. An MSW curriculum is the only curriculum which offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior.

Finally, the "grandfather clause" in the 1976 regulations has been a source of confusion for state surveyors.

#### Patient Care Dialysis Technicians

Patient care dialysis technicians should be required to demonstrate competency for and proficiency in the tasks that are assigned to them, so as to insure patient safety and quality of care. They also need to recognize signs of complications that require intervention by other health care professionals and to be attuned to psychosocial issues so as to collaborate effectively with the social worker in the unit. For these reasons, NKF supports the qualifications that are listed in proposed section 494.140(e) but, in addition, recommends that the Final Rule require certification of patient care dialysis technicians.

#### Other Personnel Issues

CMS invited comments on the role that the pharmacist should play in the dialysis facility. The participation of a pharmacist in the multidisciplinary team would be very desirable but is not practical absent a mechanism whereby CMS would provide a consulting fee for the pharmacist's services. It would be cost prohibitive for a dialysis facility to have a pharmacist on staff. However, at a very minimum a pharmacist should check each patient's prescription profile for drug interactions.

#### New Personnel Category – Social Service Assistant.

NKF recommends that the Final Rule include a new personnel category, the social service assistant. Dialysis units that have more than 75 patients per full time social worker should employ a social service assistant who- 1) As supervised by the unit social worker, performs social service tasks that are clerical in nature or involve admissions, billing, transportation arrangements, transient treatment paperwork and determines insurance coverage. Dialysis patients need assistance in accessing essential services including transportation, transient arrangements and billing/insurance issues but these tasks should not be handled by the qualified social worker since this limits the ability of the MSW to participate fully with the patient's interdisciplinary team so that optimal outcomes of care may be achieved. The conditions of coverage should define the role of a new team member who can provide social service assistance.

**Governance** (Proposed Section 494.180)

**Adequate Number of Qualified and Trained Staff**

The National Kidney Foundation has consistently maintained that dialysis care that is provided by appropriately trained personnel, and with adequate staff in relationship to acuity levels, will help to achieve recommended patient outcomes. In fact, more than 20 years ago NKF's Council of Nephrology Social Workers (CNSW) and Council on Renal Nutrition (CRN) developed staffing guidelines that reflect professional responsibilities and differences among patients. These guidelines provide formulas from which inputs and outputs can be calculated. Two decades of experience with those staffing guidelines provide the basis of our response to the following statement in the preamble to the Proposed Rule:

"In our deliberations regarding 'adequate staff,' we noted that there is no national consensus within the dialysis industry regarding the appropriate staff-to-patient ratios. However, we are interested in strengthening the existing requirement while at the same time preserving the facility's flexibility in determining the appropriate staff-to-patient ratio. One alternative to mandated staff-to-patient ratios is an acuity-based staffing system developed by each dialysis facility."

The National Kidney Foundation encourages CMS to strengthen existing requirements for staffing when the Final Rule is issued. However, our experience tells us that acuity-based staffing calculations aren't easily or readily implemented. Therefore, we propose the following patient:staff ratios. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 200 patients per social worker.

An appropriate renal dietitian-to-patient ratio is 1:100 (not to exceed 120 for temporary coverage). The ratio of 1:100 is required for the renal dietitian to have a positive impact on patient outcomes.

There should be no more than 75 patients per one full time social worker.

The ratio of care givers providing dialysis services per shift should be one staff member per four patients. The suggested ratio of technicians to nurses is about 7:3; a more optimal ration would be 6:4. For pediatric patient care, a two to threefold increase in staffing is recommended.

#### Discharge and Transfer Policies and Procedures

The Final Rule should make it clear that the requirement that the medical director sign discharge orders, contained in proposed section 494.180 (f) (4) (ii), is limited to involuntary discharges. Each facility should have procedures and policies that guide routine discharges.

#### Emergency Coverage

Section 494.80(g) (3) reads: "The dialysis facility must have an agreement with a hospital that can provide inpatient care, other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must--

- (i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.
- (ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies."

However, in rural areas, the local emergency room may be staffed by a local physician on call. If the hospital doesn't provide inpatient dialysis services, will the local emergency room personnel know where to send patients whom it cannot treat? Rural facilities need to be associated with some health care system that can provide inpatient dialysis, since most rural hospitals do not have that capability.

Thank you for your consideration of these comments.

Sincerely,



David G. Warnock, M.D.  
President, National Kidney Foundation, Inc.  
Professor and Director, Division of Nephrology  
Department of Medicine  
University of Alabama at Birmingham



**Medical Records (Proposed §494.170)**

You have proposed to eliminate the requirement that facilities have written policies and procedures for record keeping. In light of the substantial requirements for written policies and procedures under the HIPAA Privacy Rule, this proposal seems short-sighted. Perhaps the inclusion of other records-related federal and state regulations "by reference" would be appropriate for the regulatory language.

***Retention and Preservation (Proposed §494.170(c)(1) and (2))***

Under 45 CFR §164.530(j), *Standards for Privacy of Individually Identifiable Health Information*, federal regulations require that "a covered entity retain documentation for six years from the date of creation or the date when it was last in effect, whichever is later." Therefore your proposal for record retention of a five year period would seem to be in conflict with existing federal regulation and should probably be changed to six years.

Date: April 26, 2005

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
File Code: CMS-3818-P  
PO Box 8012  
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in vulnerable dialysis patient population.

I am a pharmacist and I understand the complexity of medication and its unwanted consequence side effects that may cause harm to patient.

I believe that pharmacists should be included as part of the dialysis facility multidisciplinary staff for many reasons; some reasons are listed below:

- the complex nature of drug therapy in dialysis patients (multiple),
- the pharmacokinetic complexity of drugs during dialysis (dializability),
- the vulnerability of these patients for adverse medication-related outcomes (co-morbid diseases),
- the need for storage, preparation, and administration of medications within the dialysis unit,
- the need for cost effective drug therapy,
- the training of pharmacists that prepares them to serve in dialysis facilities.

I believe above all healthcare providers; pharmacists have the most clinical knowledge in pharmacotherapy. Pharmacist is best qualify to review medication, recognize therapy duplication, prevent potential adverse drug reactions, and will have the most positive impact in this most needed patient population. I appreciate your time and consideration.

Sincerely,

Name: JOSEPHINE G. DiMASSO RPh

Signature: Josephine G. DiMasso RPh



DIALYSIS CORPORATION OF AMERICA

April 21, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8012  
Baltimore, MD 21244-8012

**RE: Response to Proposed Changes in Medicare Regulations for ESRD facilities**

**Attention: CMS – 3818 - P**

Please find attached, comments to the proposed condition for coverage for End Stage Renal Disease.

Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Joanne Zimmerman".

Joanne Zimmerman RN, CNN  
Vice President, Clinical Services

## **Response to Proposed Changes in Conditions for Coverage for End Stage Renal Disease Facilities**

### **Identifier: Infection Control**

States that an infection control officer must be an RN. I feel that if is LPN is properly trained, an LPN could act as the infection control coordinator.

Proposed rule states "place all used dialyzers and tubing in leak proof containers for transport from station to reprocessing or disposal area". I feel this rule needs more clarification as to type of container.

### **Identifier: Water Quality**

I do believe that Medicare should mandate 2 carbon tanks at each dialysis unit for patient safety.

Also states that a newly installed water system must have cultures drawn on it weekly until an established pattern of compliance can be demonstrated. I think this regulation should define "established pattern" as this could be interpreted very differently for each dialysis unit.

### **Identifier: Physical Environment**

Proposes "periodic training" for patients and staff for emergencies. I think again "periodic" should be defined.

Also proposes mandating automatic notification of a fire to emergency forces and also mandates sprinkler systems. These are very costly changes that would need to be made to existing facilities, and I think existing facilities should be exempt from this proposed regulation.

### **Identifier: Patient Assessment**

I think that 20 calendar days for completion of the patient assessment is unreasonable. The patient may only be seen 4 times prior to the 20 calendar days being up if the days fall over a weekend. I think it is more reasonable to state after 6 treatments at the facility. This will also take into account the possibly of the patient being admitted to the hospital, or possibly starting hemodialysis 2 times weekly.

Also, I think it is unnecessary to do the patient assessment again 3 months later. I do think it is important to re-evaluate the patient assessment after 3 months and make any changes that may be necessary but it is an unnecessary burden to re-do the entire assessment.

Proposal also defines unstable. One of the definitions is poor nutritional status, I think that this needs to be defined clearer because physician's opinions of poor nutritional status can vary greatly. It also states "a patient is to be considered unstable if they have unmanaged anemia or inadequate dialysis", I think that this needs to be more clear because a patient can have a small drop x 1 month in their HGB but I would not consider that patient to be unstable. I think more than 8 weeks of a HGB less than 11.0 g/dl would be considered unmanaged anemia.

**Identifier: Care at Home**

I think that the idea of home dialysis is to promote the independence of the renal patient. If a patient or caregiver is unable to provide the dialysis care, then a patient should be transported for treatment to the nearest dialysis center. The nurses at a nursing home are already over burdened and nursing home care has already deteriorated greatly. Optimum quality care can be assured at a dialysis unit where the patient care team has the knowledge and experience to care for these renal patients. I do believe it should be the responsibly of the nursing home to try to place their resident at a dialysis unit that is closest to the nursing home, if the patient wishes. Many times patients are transported much further than they need to be because they do not understand that they have the right to transfer.

**Identifier: QAPI**

I do believe that evaluating and tracking patient grievances can greatly improve the patient's dialysis experience

**Identifier: Personal Qualifications**

I do not think that all PCT's need a 3 month orientation period. Also, many PCT's find it helpful to have theory training a few weeks into training so they are able to ask questions and understand more what they are learning. I think it is essential for the PCT to receive the theory training during their orientation, but it should not be mandated that they receive that first.

**Identifier: Discharge and Transfer Policies:**

Proposed regulations states "no patient, including disruptive or non compliant patients, is discharged or transferred from the facility unless one of the following applies ....." This proposed regulations should include if it is the patient's choice.

**Note \***

Please allow six months to one year for implementation of these rules. Many policies and procedures will need developed and revised. All staff will also need education on these revisions.

April 22, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attn: CMS-3818-P  
PO Box 8012  
Baltimore, Md. 21244-8012

To Whom It May Concern:

On behalf of the Connecticut Council of Nephrology Social Workers, we are writing in response to CMS File Code 3818-P, the proposed changes to the Conditions of Coverage for Dialysis Facilities. First, we applaud the emphasis placed on maintaining the master's of social work degree in the dialysis setting and the supporting language outlining the clinical role of the master's prepared social worker that appears in the preamble to the proposed regulations. We believe that a summary of the role of the social worker should be maintained in the body of the new regulations to further clarify and build upon the description of social work that appeared in the original federal regulations. The required knowledge base for social workers should be cited (knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on patient and family) along with the social worker's role in psychosocial assessment, treatment planning, and ongoing counseling. Similarly, we believe that descriptive language outlining the roles of all team members should be maintained in the new regulations to ensure that all dialysis staff are adequately educated and trained to address the complex needs of the renal population.

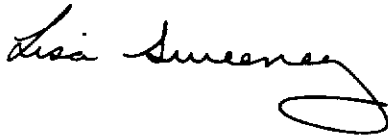
Nearly thirty years of research in the area of renal disease documents dozens of psychosocial factors affecting patient adjustment to chronic dialysis therapy. These include but are not limited to other serious co-morbid health issues, rehabilitation and employment obstacles, financial stressors, depression, and anxiety. Coupled with the demographics of an aging and more medically compromised patient population, the dialysis social worker of the 21<sup>st</sup> century is confronted with a more complex case mix than the dialysis social worker of the 1970's. As such, we believe that the new federal regulations must address the issue of caseload complexity via caseload ratios. We are convinced that one critical way to maintain a standard of quality care is by limiting the caseloads of master's prepared social workers. Currently, Texas and Nevada have laws in effect mandating caseloads not to exceed 100 patients per full-time social worker. We endorse this ratio and we believe that this specific caseload ratio should be included in the new federal regulations.

To further support the importance of caseload ratios, we wish to cite a research study conducted by our own Connecticut Council of Nephrology Social Workers in conjunction

with the New England Area Renal Social Workers. (Bogatz, Colasanto, & Sweeney, Nephrology News and Issues, January 2005) Of the 98 social workers surveyed, 72% had a median caseload of 125 patients with caseloads as high as 170. Sixty-eight percent of social workers reported that they did not have enough time to do casework or counseling and 36% spent an excessive amount of time doing clerical, insurance, and billing tasks. One respondent stated "the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients are being denied access to quality social work services".

In conclusion, we appreciate the opportunity to make comment on the proposed conditions of coverage. To summarize, we support maintaining the MSW credential for social workers with the addition of descriptive language outlining the social work role. We believe that a **maximum** caseload ratio of 100 patients per full-time social worker should be included to ensure patient access to quality social work services. On behalf of the Connecticut Council of Nephrology Social Workers, we look forward to new and updated federal regulations that will ensure optimal quality of care for the hundreds of thousands of renal patients requiring chronic dialysis therapy.

Sincerely,

A handwritten signature in cursive script that reads "Lisa Sweeney". The signature is written in black ink and includes a large, stylized loop at the end of the last name.

Lisa Sweeney MSW, LCSW  
President, Connecticut Council of Nephrology Social Workers



College of Pharmacy  
Department of Clinical Pharmacy  
26 South Dunlap Street  
Memphis, TN 38163

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April 25, 2005

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
File Code: CMS-3818-P  
PO Box 8012  
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility.

I am currently on the faculty at the University of Tennessee as an Associate Professor in the Department of Pharmacy and an Assistant Professor in the Department of Medicine, Division of Nephrology. I joined the faculty after completing fellowship training in nephrology pharmacy and have remained actively engaged in nephrology as a focus of my practice, teaching, and research activities. As a pharmacist who specializes in nephrology, I believe I am qualified to comment on the need for pharmacists' involvement in dialysis facilities.

Based on my experiences in dialysis facilities both in Virginia and Tennessee and the review of information on drug related problems in the end stage renal disease (ESRD) population, it is clear that there is a need for more attention on appropriate use of medications. Specifically, pharmacists can address this need and should be included as part of the dialysis facility staff for the following reasons:

- Complex nature of drug therapy in dialysis patients: Increases the risk of adverse drug reactions, patient nonadherence with drug therapy, and drug interactions
- Influence of dialysis on drug disposition: Altered pharmacokinetics of drugs during dialysis (eg. drug removal by the dialyzers, changes in drug distribution)
- Vulnerability of these patients for adverse medication-related outcomes: Changes in drug disposition during dialysis and decreased elimination of certain agents that depend on elimination by the kidney make adverse reactions and outcomes more likely
- Need for storage, preparation, and administration of medications within the dialysis unit: Introduces more risk of medication errors; pharmacists could facilitate the current processes that exist in dialysis facilities
- Need for cost effective drug therapy: Pharmacists have a unique perspective in evaluating the cost vs. benefit of various medication regimens
- Changing nature of drug therapy that will arise due to the MMA



- Training of pharmacists that prepares them to serve as consultants to dialysis facilities: Includes general training and opportunities for specialized training (eg. residencies in nephrology, nephrology fellowships, etc.)

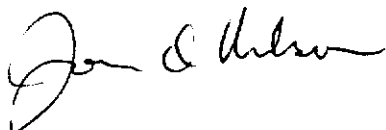
Benefits of pharmacists have been realized in management of disease states and conditions that affect the ESRD population, namely diabetes and hypertension, as well as in management of associated secondary complications; anemia, metabolic bone disease, hyperlipidemia, malnutrition. Pharmacists are also well trained to recommend appropriate dose adjustments, a particularly useful resource when drugs not as common in the ESRD population are being prescribed, and to provide patient education on medication regimens.

Specific recommendations that would facilitate the process of integrating pharmacists in the dialysis setting and allow for the potential benefits of such involvement on patient outcomes to be realized include:

1. Addition of a pharmacist to the multidisciplinary dialysis team in dialysis facilities.
2. A routine patient care assessment of dialysis patients that includes a medication review by a pharmacist.
3. Conduct of medication reviews on a monthly basis. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Participation by a pharmacist in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
5. Development and maintenance of appropriate policies for the safe storage, preparation and administration of medications within dialysis facilities. These policies should be developed and maintained in consultation with a pharmacist.
6. Provision of adequate compensation for these services as opposed to making the addition of a pharmacist an unfunded mandate.

It is certainly noteworthy that the Proposed Rule on "Personnel Qualifications" acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in the dialysis patient population. There is clearly a need to decrease medication errors in the ESRD population and to more appropriately manage the associated complications of chronic kidney disease through both pharmacologic and nonpharmacologic approaches. Pharmacists have adequate training and expertise to help reach these goals. In closing I strongly support the addition of a pharmacist to the multidisciplinary team of health care providers in dialysis facilities.

Sincerely,



Joanna Q. Hudson, Pharm.D, BCPS  
Associate Professor  
The University of Tennessee  
Departments of Pharmacy & Medicine (Nephrology)

**Wheeling Renal Care  
500 Medical Park, Suite 100  
Wheeling, WV 26003  
(304) 242-7770**

April 26, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
PO Box 8012  
Baltimore, MD 21244-8012  
**Attn: CMS-3818-P 156**  
**Re: (Proposed Section 494.140 Personnel Qualifications)**

To Whom It May Concern:

This letter is being written in response to the CMS Conditions of Coverage, especially in regards to the Social Work Qualifications. Please consider this recommendation for the conditions listed under Social Work Qualifications.

I am making a recommendation to keep the "grandfather clause" - which substituted an experience criterion, "having served at least 2 years, 1 year of which was in a dialysis setting"; and to keep the criterion requiring a consultative relationship to a social worker with a master's degree (MSW).

I believe there is a need to retain at least this part of the grandfather clause and consideration should be given to units in rural areas. Limiting the wording to **MSW's only** would be a barrier to social worker's entering the dialysis field, especially in our rural area.

Since MSW's are not readily available in rural areas, there should be an allowance made in the guidelines to include a SW holding a Bachelor's Degree (BSW) to have a consultative relationship with a MSW. It may be helpful to find actual proof that a BSW with many years of experience is **not** effective in the dialysis setting prior to making the proposed changes.

I would like to present an example to further explain:

In our rural area, when I first began to work in dialysis, I had replaced a "Qualified" social worker (a MSW). I was hired because she was not able to do the job effectively. Currently, I am a MSW (Director of Social Services) and we have a BSW who has a consultative relationship with me. The BSW has *22 years of full-time experience* as a social worker (she used to be my supervisor). She has been a dialysis SW for over 6 years and is *well qualified to be a renal social worker*. She is *extremely competent in all areas of dialysis* and has also attended National Meetings for Continuing Education in the Renal Field on a regular basis.

My recommendation is to maintain the grandfather clause because it may be very difficult for units in rural areas to employ a social worker at the Master's Level. There should be some flexibility in the guidelines to include BSW's in Renal Social Work as long as they are in a consultative relationship with an MSW.

Please give consideration to this request. Thank you for an opportunity to voice my concerns.

Sincerely,

A handwritten signature in cursive script that reads "Mary Lou Furbee".

Mary Lou Furbee, MSW  
Director of Social Services

April 28, 2005

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention : CMS –3818-P  
PO Box 8012  
Baltimore, MD 21244-8012

Sarah Mc Closkey, LSW  
Williamsport and Lock Haven Dialysis Clinics  
1660 Sycamore Road  
Montoursville, Pa 17754

To Whom It May Concern:

I would like to reply to the proposed Conditions of Coverage for CMS-3818-P Subpart D – 494.140. As a licensed master's level social worker I feel it is imperative to keep the master's requirement for social workers because we are uniquely trained to handle the numerous and complicated psychosocial issues presented by ESRD patients. The recognized role of the nephrology social worker is to: provide initial and continuous patient evaluation and assessment including patients' social, psychological, financial, cultural and environmental barriers to coping to ESRD and their treatment regime; provide patients and their support networks emotional support, encouragement and supportive counseling; provide assistance with adjustment and coping to CKD, comorbidities and treatment regimes; patient and family education; crisis intervention; provision of information and community referrals, assistance with advance directives and self-determination issues; group work including support groups and patient advocacy groups; case management with community resources, state agencies and federal programs; assisting patients with obtaining maximum rehabilitative status (including: ongoing assessment of barriers to patient goals of rehabilitation; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); provide staff in-service education regarding ESRD psychosocial issues; participate in the facility's quality assurance program; mediate conflicts between patients, families and staff; participate in interdisciplinary care planning and collaboration, and patient advocacy (Beder, 1999; Beer, 1995; Dobrof, Dolinko Lichtiger, Uribarri & Epstein, 2001; Fortner-Frazier, 1981; Kimmel et al. 1995; McKinley & Callahan, 1998; McKinley, Schrag & Dobrof, 2000; Merighi & Ehlebracht, 2004c; Nichols & Springford, 1984; Oldenburg, Macdonald, & Perkins, 1988; Petrie, 1989; Russo, 2002). The scope of these tasks is congruent with those traditionally related to medical social work in the realms of prevention, palliation, treatment and advocacy efforts directed at making healthcare more patient centered (Dhooper, 1994).

Due to the complex nature of the renal patient's needs and issues, interdisciplinary collaboration of care for renal patients by this team has been found to be necessary for optimal delivery of services. A multidisciplinary approach (including a Master's level social worker) to CKD care has been shown to be effective in improving patient outcomes, and is the recommended method of providing CKD patient care (Corsini & Hoffman, 1996, Dunn & Janata, 1987; Gitlin, Lyons, & Kolodner, 1994; Goldstein, Yassa, Dacouris & McFarlane, 2004; Houle, Cyphert, & Boggs, 1987; Warady, Alexander, Watkins, Kohaut & Harmon, 1999).

Our task as social workers is vital in the health and survival of our patients. However, we are often asked to do tasks that take up a good deal of time and limit our ability to assist our patients with their psychosocial issues. I would to propose the addition of language that would prevent or limit social workers from doing clerical work, making transportation arrangements, dealing in insurance matters and arranging transient trips. Russo (2002) found that 100% of nephrology social workers surveyed felt that transportation was not an appropriate task, yet 53% of respondents were responsible for making transportation arrangements. Russo (2002) found that 46% of nephrology social workers were responsible for making transient arrangements, yet only 20% were able to do patient education. Tasks such as clerical duties, admissions, billing and insurance matters prohibit effective nephrology clinical social work intervention to patients (Callahan, Witten & Johnstone, 1997; Russo, 2002). Promoting Excellence in End-of-Life Care (2002), a national program office of The Robert Wood Johnson Foundation recommends that dialysis units discontinue using Master's level social workers for clerical tasks (such as arranging transportation) in order to ensure that nephrology social workers have sufficient time for clinical service provision to their patients and their families. Merighi & Ehlebracht (2004b; 2004c; 2005) in an exhaustive survey of 809 national nephrology social workers found that:

- 94% of social workers did clerical work (faxing, copying), and that 87% of those respondents found these tasks to be outside the scope of their social work training
- 61% of social workers were solely responsible for arranging patient transportation
- 57% of social workers were responsible for making transient arrangements, taking 9% of entire social work time
- Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs
- 26% of social workers were responsible for initial insurance verification
- 43% of social workers tracked Medicare coordination periods
- 44% of social workers are primarily responsible for completing admission packets

- Alarmingly, 18% of social workers were involved in collecting fees from patients. This can negatively affect the therapeutic relationship and decrease patient trust.
- The more that nephrology social workers are involved with insurance/billing, the lower their job satisfaction, particularly among social workers who collect fees from patients
- Nephrology social work job satisfaction is related to amount of time spent counseling and patient education (significantly higher job satisfaction) and insurance-related, clerical tasks (significantly lower job satisfaction)
- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time counseling and assessing patients
- Nephrology social workers who spend more time doing insurance, billing and clerical activities report more emotional exhaustion.
- Nephrology social workers who spend more time doing counseling and patient education report less emotional exhaustion. The authors indicate that these correlations may be indicative of the fact that providing education and direct counseling to patients and family members are activities that are commensurate with the professional training and education of master's-level social workers (unlike billing, insurance and clerical tasks).

On average, I spend 25-50% of my time dealing with insurance issues. I have spent numerous hours arguing with insurance companies, Medicare and researching insurance questions that would have been much better spent with my patients. I would like to propose that a requirement for someone to specialize in insurance issues be made part of the team. This becomes even more important with the upcoming addition of prescription drug coverage to Medicare. I have already been questioned about the changes. When they go in effect, I suspect I will spend the majority of my time answering questions and explaining the benefit.

Another change I would like to propose is the addition of a patient to social worker ratio. With 150 patients, I find it very difficult to meet the needs and demands of all my patients in a timely and effective manner. While some are very high functioning and need little, many more require a great deal of my time and I am often forced to prioritize patients to ensure that the neediest are addressed first. I wish to propose a ratio of 1 social worker to every 100 patients in order to ensure that all patients' needs are met in a timely manner. Texas mandates that nephrology social workers have a patient ratio of 75 to 100 patients per full time social worker. Nevada has a mandated ratio of one full time social worker per 100 dialysis patients. Oregon Council of Nephrology Social Workers recommends a ratio of 100 patients to one full time social worker. Social workers report that high caseloads result in a lack of ability to provide adequate clinical services (Merighi, & Ehlebracht, 2002). Merighi, & Ehlebracht, (2004a) in a national survey of dialysis social workers, found that only 13% of full

time social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, 47% had caseloads of more than 100 patients. High nephrology social work caseloads result in lower patient satisfaction and less successful patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). Estrada & Hunt (1998) recommend that increased time is needed for social workers to fully assess patients' psychosocial status. Merighi & Ehlebracht (2005) found that nephrology social workers spend more time providing counseling to patients when they have lower patient caseloads. In one study of nephrology social workers (Bogatz, Colasanto & Sweeney, 2005) 68% of all social workers did not have enough time to do casework or counseling; 62% did not have enough time to do patient education; 36% spent excessive time doing clerical, insurance and billing tasks. One participant stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients are being denied access to quality social work services.' (P.59). Social workers had caseloads as high as 170 patients, 72% of social workers had a median caseload of 125 patients. Social workers have indicated that large caseloads hinder their ability to provide clinical interventions (Bogatz, Colasanto & Sweeney, 2005).

In conclusion, I feel that masters level social workers are the best qualified to meet the varied and complicated psychosocial needs of ESRD patients. I also feel that social workers should be freed of such time consuming burdens as doing clerical work, making transportation arrangements, dealing in insurance matters and arranging transient trips. Our time is much better spent directly addressing the needs of our patients to improve their quality of life and outcomes. I also feel that limiting the number of patients on our caseload will also greatly impact our ability to serve our patients. Thank you for your time and consideration in this matter.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Sarah Mc Closkey', followed by the text 'LSW'.

Sarah Mc Closkey, LSW  
Nephrology Social Worker

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Comments on the Conditions of Participation for ESRD services  
Re: CMS-3818-P  
April 2005

1

First I want to support the general new direction to focus on provision of quality care with attention to outcomes of care.

Since I am a Licensed Clinical Social Worker, I will be focusing my comments more specifically on areas that relate to my discipline.

§ 494.10 Definitions: Dialysis Facility

I propose that a new category be added for dialysis provided in a nursing home setting. It would be "staff assisted skilled nursing home dialysis." In nursing homes, dialysis patients typically have the dialysis performed by staff, rarely by a trained helper and very rarely by the patient independently. The situation is quite different than "home dialysis" in which PD or home hemodialysis is performed by the patient and/or helper. Patients in nursing homes are generally very frail and are not able to perform many activities of daily living in an independent manner. They would need special oversight by trained staff in order to have dialysis in the nursing home.

§ 494.70 Condition: Patients' Rights

I recommend an addition to (a)(3) as: Facilities will provide a private setting for confidential interviews with patients and families.

This is in keeping with HIPAA privacy policy.

I am favorable of the mention of "including advance directives" under patients' rights.

I recommend adding as (a)(6): Upon completing a valid DNR and adequately informing the facility of their DNR, the patient's DNR wishes will be followed.

There are some dialysis companies that have allowed individual units to ignore such patient wishes. If a facility does not honor a properly executed DNR, the facility is clearly not abiding by their responsibility to respect the rights of patients.

I favor adding new (a)(17) Have access to a qualified social worker and dietitian as needed. Social workers and dietitians need to have reasonable caseloads so they can be available to patients, especially in their first few months of treatment as they are getting oriented. When social workers and dietitians are expected to work in multiple units with high caseloads, the patients are not receiving adequate services to achieve success in adapting to dialysis.

And add new (a)(18) refuse cannulation by a staff if access problems occurred with that staff in the past until evidence of retraining is provided. Patients may request another staff person to observe cannulation. Be informed self-cannulation is possible and offered such training. Patients have the right to protect their access as only so many sites are available in the body.

Add new: (a)(19) Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of illness and any behavior that negatively impacts the patient's health.

Add to (b)(1): Receive counseling and support from the team to resolve behavioral difficulties and be informed of behaviors that will lead staff to notify police or refer for evaluation of risk to self or others. Facilities should be encouraged to engage patients in counseling to resolve difficulties before they escalate.

Add: new (b)(2) "Not be involuntarily discharged from the facility for non-adherence with the treatment plan, or other actions which harm only the patient. The facility must show that the patient's behavior is putting other patients or the facility operations at risk before they may discharge.

Under current proposed condition (b)(2), delete words "reducing" ... "on-going care" or redefine them. The current wording may lead to ambiguity.

#### 494.80 Condition Patient Assessment

In first sentence, change phrase "social worker" to "qualified social worker." This is to reduce ambiguity.

Under (a)(1), add at the end of the current sentence: "and functioning and well-being using the SF-36 or other standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component summary (MCS) score and all domains of functioning and well-being measured by that survey."

There is sufficient literature supporting the fact that there is value in using the PCS and MCS scores to independently predict morbidity and mortality among ESRD patients. These scores can be obtained from any of the tools currently in use to measure functioning and well-being. These scores can be improved through qualified social work interventions.

Wording of (a)(7) should be changed to: "Evaluation of psychosocial status (such as, but not limited to: coping with chronic illness, psychosocial barriers to optimal adjustment, social role disturbance, rehabilitation issues and quality of life.)"

All patients have a psychosocial status, but some patients may not have, or may not perceive that they have, psychosocial needs. The social worker would be the staff responsibility for evaluation of the (a)(7) items. I support the new Conditions containing social work outcome-based requirements. This requires that the social workers be allowed a reasonable patient to staff ratio in order to complete such outcome based work for the benefit of improved patient care.

I support your conditions for the personnel making up the interdisciplinary team and the retention of the word "comprehensive" regarding the assessment.

Under frequency of assessment for new patients (b), I recommend 30 days rather than 20 days to complete the initial assessment. Recommend new wording for (b)(1): "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment." There can be so many barriers to gathering needed information in the first weeks of dialysis for a new patient; the patient may be hospitalized, may be very ill from uremia and unable to fully cooperate, etc. I agree with a comprehensive reassessment 3 months after the completion of the initial assessment. Then moving to a yearly assessment for stable patients and monthly assessment for unstable patients as the new conditions state.

I suggest a change of language for (d)(iii) "Significant change in psychosocial needs" which can be changed to "Significant change in psychosocial status." This brings it into alignment with the lines before and after it that refer to: "health status" and "nutritional status". Add new (d)(2)(v): "Physical debilitation per patient report, staff observation or reduced physical component summary (PCS) score on a validated measure of functioning and well-being."

Add new (d)(2)(vi): "Diminished emotional well-being per patient report, staff observation or reduced mental component summary (MCS) score on a validated measure of functioning and well-being."

Add new (d)(2)(vii): "Depression per patient report, staff observation or validated depression screening survey."

§494.90 Condition: Patient plan of care

Add as (a)(3): "Psychosocial status. The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status." Psychosocial issues often negatively impact health outcomes of patients and diminish patient quality of life. Psychosocial status must be considered equally as important as other aspects of the care plan.

Add new (a)(6) "Home dialysis status. All patients must be informed of all home dialysis options, including CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis and nocturnal home hemodialysis and be evaluated as a home dialysis candidate."

I concur with the standard outlined to track transplant referrals.

The requirement for an MD to see patients on a monthly basis is reasonable except for rare circumstances of geographically isolated areas, particularly in the Pacific Islands, which should be given some specific exception but the rule should not be so loose that others, who do not really need an exception, take advantage of it.

494.110 Condition Quality Assessment and performance improvement.

Add: (1) "The program must include, but not be limited to, an ongoing program that achieves measurable improvement in physical, mental and clinical health outcomes and reduction of medical errors by using indicators or performance measures associated with improved physical and mental health outcomes and with the identification and reduction of medical errors."

Add new: (2)(iii) "Psychosocial status."

Add new: (2)(ix): "Functioning and well-being as measured by physical component summary (PCS) and mental component summary (MCS) scores (or other equally valid measure of mental and physical functioning and vocational status using the same categories as reported on the CMS 2728 form" These scores can provide a baseline and ongoing basis for QAPI activities to improve patient rehabilitation outcomes.

494.140 Condition Personnel qualifications

Change language of (d)(2) to: "Social worker. The facility must have a qualified social worker who meets the licensing requirements for Masters Degree level social work practice in the State in which he or she practices."

Add (d)(3) social worker is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping with ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to ESRD, comorbidities and treatment regimes, including diagnosing and treating mood disorders, providing patient and family education; helping to overcome barriers to transplantation and home dialysis; crisis intervention; assist with completing advance directives; assist with rehabilitative goals; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration and advocating on behalf of patients when appropriate. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide or other staff person who is responsible for these tasks."

Add (e) Standard: " Case aide. Dialysis units that have more than 75 patients per full time social worker must employ a case aide who performs clerical tasks involving admissions, transfers, billing, transportation arrangements, transient arrangements, transient treatment paperwork and verifies insurance coverage."

Patients have need for many services but it is not appropriate for a social worker to do the clerical aspects of care. The qualified social worker can provide interventions that can maximize patient outcomes and improve the patient's quality of life.

Thank you for considering my suggestions about the proposed Conditions of Participation.

Sincerely,

A handwritten signature in black ink, appearing to read "Fran Ryan, LCSW".

Fran Ryan, LCSW  
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April 27, 2005

Mark B. McClellan, MD, PhD, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
File Code: CMS-3818-P  
PO Box 8012  
Baltimore, MD 21244-8012

Dear Dr. McClellan:

We are writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically, we wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. We appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in vulnerable dialysis patient population.

Over the last 15 years, colleagues affiliated with The Peters Institute of Pharmaceutical Care at the University of Minnesota have been preparing practitioners and students to assume responsibility for addressing drug-related morbidity and mortality by ensuring the safe and effective use of medications (*Pharmaceutical Care Practice: The Clinician's Guide*. Cipolle RJ, Strand LM, Morley PC. McGraw Hill 2004). Data on file at the Peters Institute documenting patient outcomes attributable to the practice of pharmaceutical care (referred to by the federal government as "medication therapy management services") is based on over 60,000 patient encounters. We believe that pharmacists should be integral members of the health care team serving the complex drug-related needs of dialysis patients.

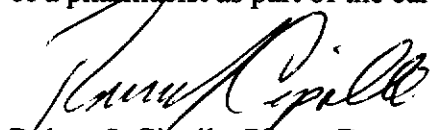
We believe that pharmacists should be included as part of the dialysis facility staff due to:

- the complex nature of drug therapy in dialysis patients,
- the pharmacokinetic complexity of drugs during dialysis
- the vulnerability of these patients for adverse medication-related outcomes,
- the need for cost effective drug therapy,
- the training of pharmacists that prepares them to serve as consultants to dialysis facilities.
- the need for storage, preparation, and administration of medications within the dialysis unit,
- the changing nature of drug therapy that will arise due to the MMA, and

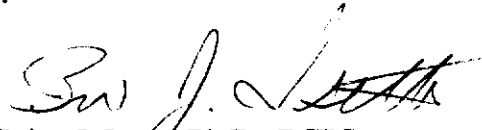
Specifically, we would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a pharmacist with experience or training in nephrology pharmacotherapy.
2. The routine patient care of dialysis patients should include a comprehensive pharmacotherapy assessment, including the identification of drug therapy problems, conducted by a pharmacist.
3. Pharmacotherapy follow-up evaluations including documentation of progress in achieving goals of therapy should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care nursing facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols and care plans within dialysis to assure cost-effective drug use.
5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.

Pharmaceutical care services have been demonstrated to save substantial health care resources, while ensuring that individual patients receive effective and safe drug therapies. Because medications play such a vital role in the care of patients with end-stage renal disease, inclusion of a pharmacist as part of the care team is imperative.



Robert J. Cipolle, Pharm.D.  
Director and Professor  
Peters Institute of Pharmaceutical Care



Brian J. Isett, Ph.D., BCPS  
Associate Professor  
Peters Institute of Pharmaceutical Care

April 26, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3818-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

RE: Proposed Rule: Conditions of Participation for Coverage of End Stage Renal Disease Facilities (CMS-3818-P)

I am writing to offer comments regarding the above referenced proposed regulations published February 4, 2005. Enclosed please find one original and two copies. My comments are motivated by the desire to ensure that Medicare beneficiaries and others who require dialysis receive the best possible psychosocial services addressed by the dialysis facility. As a renal social worker, I want to address these proposed regulations in detail as follows:

**Issue Identifier: 494.70 Patients' Rights (b) Standard: Right to be informed regarding the facility's discharge and transfer policies**

**Comment:** I recommend adding to b1, "Receive counseling and support from the team to resolve behavioral issues and be informed of behaviors that will lead staff to notify police or refer for evaluation of risk to self or others." In general, facilities should be encouraged first to try counseling to resolve difficult situations.

I recommend adding (new 2): "Not be involuntarily discharged from the facility for non-adherence with the treatment plan, including missing or shortening in-center hemodialysis treatments, excessive fluid weight gain, or lab tests that would suggest dietary indiscretions unless it can be shown that the patient's behavior is putting other patients or the facility operations at risk." I recommend the above language because the ESRD Networks and the preamble of these proposed Conditions for Coverage have both stated that non-compliance should not be a basis for involuntary discharge from lifesaving dialysis treatment. Patients are often not educated as to the reasons why these behaviors may be harmful to them, and it is therefore inappropriate to refuse them care due to their lack of knowledge.

**Issue Identifier: 494.80 Patient Assessment (a) Standard: Assessment Criteria**

**Comment:** I recommend changing the language of "social worker" in the first sentence to "qualified social worker" to clarify any ambiguity of the social work role.

I recommend adding (a1) "...and functioning and well-being using the SF-36 or other standardized survey that permits reporting of or conversion to a physical component summary (PCS) score and mental component summary (MCS) score and all domains of functioning and well-being measured by that survey. If the MCS or mental health domain score is low, assess for major depression using the PHQ-2 or another validated depression survey or refer the patient to further mental health evaluation." My rationale is that the preamble to these proposed regulations discuss the importance of measuring functioning and well-being – but state that there



was “no consensus” about which measure to use. In fact, the literature clearly supports the value of the PCS and MCS scores to independently predict morbidity and mortality among tens of thousands of ESRD patients – and these scores can be obtained from any of the tools currently in use to measure functioning and well being. The composite scores (PCS and MCS) have been proven to be as predictive of hospitalization and death as serum albumin or Kt/V. Scores can be improved through qualified social worker interventions.

I support the language as proposed of a2, a3, a4, a5 and a6.

I recommend changing a7 to read: “Evaluation of psychosocial needs (such as but not limited to coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality and morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses, including loss of income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid, as well as social role disturbances, dependency issues, diminished quality of life, relationship changes, transplantation referrals, participation in self-care, activity level, rehabilitation status).” Elaborating what “psychosocial issues” entails will ensure national coherence of the exact psychosocial issues that must be assessed for each patient.

I support the language of a8.

I recommend adding (a9)(new i): “The facility must include in its evaluation a report of self-care activities the patient performs. If the patient does not participate in care, the basis for non-participation must be documented in the medical record (i.e., cognitive impairment, refusal, etc.)” LifeOptions research has found that patients on dialysis 15 years or longer who participated actively in their own care did better; follow-up research with a random sample of 372 in-center hemodialysis patients found participation in self-care is correlated with higher functioning and well-being, which, in turn, predicts reduced hospitalization and mortality.

**Issue Identifier: 494.140 Condition – Personnel Qualifications**

**Comment:** I would recommend either renaming this section “Personnel Qualifications and Responsibilities” or adding a discussion of responsibilities of the team members, not just the medical director. It is important to delineate personnel responsibilities in some fashion to ensure that there is parity in the provision of services to beneficiaries in every dialysis unit in the country. This is especially important regarding qualified social work responsibilities. Currently many masters-level social workers are given responsibilities and tasks that are clerical in nature and that prevent the MSW from participating fully with the patient’s interdisciplinary team so that optimal outcomes of care may be achieved. Tasks that are clerical in nature or involve admissions, transportation, travel, billing, and insurance prevent nephrology social workers from performing the clinical tasks central to their mission. One recent survey (Merighi & Ehlebracht, 2004, 2005) found that 94 per cent of social workers did clerical tasks and that 87 per cent of those respondents considered these tasks to be outside the scope of their social work training. In the Promoting Excellence in End of Life Care 2002 report, **End Stage Renal Disease Workgroup Recommendations to the Field**, it was recommended that dialysis units

discontinue using masters level social workers for clerical tasks to ensure that they will have sufficient time to provide clinical services to their patients and their families.

**Issue Identifier: 494.140 Condition – Personnel Qualifications (d) Standard: Social Worker**

**Comment:** I recommend changing the language of (d) to: *Social Worker*. The facility must have a qualified social worker who (1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school or social work accredited by the Council on Social Work Education; (2) Meets the licensing requirements for social work practice in the State in which she/he is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social psychological, cultural and environmental barriers to coping with ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but is qualified to supervise the case aide who is responsible for these tasks.

Clinical social work training is essential to offer counseling to patients and families for complex psychosocial issues related to ESRD and its treatment regimes. Changing the language of this definition will make it congruent to that of a qualified social worker. I also support the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, it is important to recognize the importance of the professional social worker and I believe there is a need for the requirement that the social worker have a master's degree. As the ESRD population has become increasingly more complex from both a medical and psychosocial perspective, the training that a qualified masters degree social worker completes is essential.

Thank you for the opportunity to provide comments on these proposed regulations. Please feel free to contact me should you have any questions.

Sincerely,

Jeff Harder, MSW, LICSW  
Nephrology Social Worker  
206-598-4676  
Email: [Maxx11@comcast.net](mailto:Maxx11@comcast.net)

68  
9704 Perry Farms Drive  
Perry Hall MD 21128

April 21, 2005

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3818-P  
PO Box 8012  
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding various aspects of the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities.

My comments are based on my experience of providing social work services to adult and pediatric hemodialysis and peritoneal dialysis patients for the past 13 years. I have worked in both for-profit and not-for-profit dialysis clinics.

Sincerely,



Christopher Simon, MSW, LCSW-C  
Social Worker

**Patient Plan of Care (Proposed Sec. 494.90)**  
pp. 6208-6209

From the text:

“Complex emotional and social factors affect the dialysis patient . . .”  
“We are soliciting comment regarding the most effective way to address these factors within a patient plan of care requirement that supports an effective level of emotional and social well-being for the patient.”

Comment:

Regular measurement of a patient's perceived quality of life should be mandated as part of the care planning process. Numerous studies (DeOreo, 1997; Mapes, et al. 2003) have shown that “quality of life” is an important indicator/predictor of morbidity and mortality outcomes. There are already several assessment instruments that measure the emotional and social well-being of patients and that are widely accepted in the dialysis community. Consensus on a single assessment tool may not be needed, as long as there is a requirement that the instrument is valid and reliable, dialysis specific and can provide physical component summary and mental component summary scores.

From the text:

“We are soliciting comments regarding the potential for an outcome-based requirement for social services in the patient plan of care”.

Comment:

Developing meaningful outcome-based requirements specific to social services has been attempted within my local (state) dialysis provider community with little success. This may be due, in part, to the nature of social work, which requires respect for patient preferences and recognizes and supports individual autonomy in decision-making.

It is also true that most outcomes in the dialysis clinic are the result of a collaborative effort between the patient and all members of the multidisciplinary team. Impediments to achieving a particular outcome will vary from patient to patient depending on each individual person's circumstances and, in many cases, the impediments are multi-factorial. In all cases, a team approach is best suited to achieving the desired outcome. Artificial distinctions that assign responsibility to one member of the treatment team for specific outcomes are not in keeping with a multi-disciplinary approach to patient care.

However, given the relatively minimal attention paid to the mental health of patients in the proposed rule and in general practice, I would suggest that depression screening be considered as a possible requirement for social services in the patient plan of care. Multiple studies report a high prevalence of untreated depression in dialysis patients and find that depression is an independent predictor of death (Andreucci et al., 2004; Kimmel, 1993; Kimmel, 2000; Wuerth, Finklestein & Finklestein, 2005).

**Personnel Qualifications (Proposed Sec. 494.140)**

Page 6222

From the text:

**4. Social Worker (Proposed Sec. 494.140(d))**

We are proposing in Sec. 494.140(d) to retain the existing requirements for social workers at Sec. 405.2102(f). . .

While nonprofessional personnel may serve in a supportive capacity, we do not believe they can be employed in place of a fully-credentialed MSW.

We recognize that dialysis patients also need other essential services including transportation and information on Medicare benefits, eligibility for Medicaid, housing, and medications, but these tasks should be handled by other facility staff in order for the MSW to participate fully with the patient's interdisciplinary teams so that optimal outcomes of care may be achieved.

Comment:

For the reasons stated in the discussion of the proposed rule, I do support the continuing requirement that the dialysis clinic employ a qualified master's degree social worker (MSW).

There will no doubt be an effort by some to argue that the requirement is too strict and cannot be met in all geographic areas. I believe that this argument arises largely from a desire to control personnel costs. Many dialysis providers have marginalized the role of the social worker by relegating to her/him tasks that are essentially "clerical" in nature; they may now seek to change the definition of a qualified social worker, arguing that the work being performed does not require a Master's degree social worker. Should that be allowed to happen, patient care will suffer.

In order for the MSW to participate fully with the patient's interdisciplinary teams so that optimal outcomes of care may be achieved, the proposed rule should include a requirement for an *additional* multidisciplinary team member who is responsible for providing patients with the essential services they need, including transportation and information on Medicare benefits, eligibility for Medicaid, housing, and medications.

Many dialysis clinics have successfully used a model that incorporates a "case aide" to perform these functions under the direction of the master degree Social Worker.

From the text:

“One alternative to mandated staff-to-patient ratios is an acuity-based staffing system developed by each dialysis facility. This type of system would take into account the number of patients treated on each shift, individual patient characteristics, patient needs, the expertise and experience levels of facility staff, the physical layout of the facility, available technology, and the availability of support services. An acuity-based staffing plan, including some or all of the criteria listed above, could be developed by the nurse responsible for nursing services in the facility and approved by the medical director.

It could also be incorporated into the facility's QAPI program (see Sec. 494.110) as a means of achieving desired outcomes of care specified in the facility's individual patient plans of care (see Sec. 494.90). We are soliciting public comment on whether we should include a requirement for an acuity-based staffing plan in Sec.

494.180(b)(1) to ensure that every dialysis facility has “adequate staffing” and appropriate staff-to-patient ratios to meet the needs of its patients”.

Comment:

For many years, the Council of Nephrology Social Workers has promoted an acuity-based model for social work staffing. This model, widely distributed to all dialysis units, has largely been ignored by dialysis providers, which routinely employ patient-to-social work ratios of 125-300:1. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (such as the model developed by CNSW), or set a national patient-social worker ratio.

Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). Social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, & Ehlebracht, 2004).

## References:

Andreucci, V. E., et al. Dialysis Outcomes and Practice Patterns Study (DOPPS) data on medications in hemodialysis patients. *Am J Kidney Dis.* 2004 Nov 44(5 Suppl 3):61-7

Medical and patient questionnaires show that depression in hemodialysis patients is common, frequently under diagnosed, usually untreated, and associated with increased rates of mortality and hospitalization.

Callahan, M. B., Moncrief, M., Wittman, J., & Maceda, M.. Nephrology social work interventions and the effect of caseload size on patient satisfaction and rehabilitation interventions. *Journal of Nephrology Social Work*, 18, 66-79, 1998

DeOreo PB. Hemodialysis patient-assessed functional health status predicts continued survival, hospitalization, and dialysis-attendance compliance. *Am J Kidney Dis.* 1997 Aug;30(2):204-12.

The SF-36 provided a good screening tool for patients at high risk for death, hospitalization, poor attendance, and depression. The physical component summary (PCS) score was as significant a predictor of mortality as was the normalized protein catabolic rate or the delivered Kt/V. Patients with a PCS score below the median for our patients (< 34) were twice as likely to die and 1.5 times more likely to be hospitalized as patients with PCS scores at or above the median score. Either a low PCS score or a low mental component summary (MCS) score correlated with the number of days of hospitalization.

Kimmel, P., Peterson, R., Weihs, K., Simmens, S., Boyle, D., Verne, D., Alleyne, S., & Cruz, I. Veis, J. Multiple measurements of depression predict mortality in a longitudinal study of chronic hemodialysis outpatients. *Kidney International*, 2000, 5(10), 2093-2098.

Higher levels of depressive affect in ESRD patients treated with HD are associated with increased mortality. The effects of depression on patient survival are of the same order of magnitude as medical risk factors.

Kimmel PL et al Survival in hemodialysis patients: the role of depression. *J Am Soc Nephrol.* 4(1):12-27, 1993.

Mapes DL, Lopes AA, Satayathum S, McCullough KP, Goodkin DA, Health-related quality of life as a predictor of mortality and hospitalization: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Kidney Int.* 2003 Jul;64(1):339-49.

Lower scores for the three major components of HRQOL were strongly associated with higher risk of death and hospitalization in hemodialysis patients, independent of a series of demographic and co morbid factors. A 10-point lower PCS score was associated with higher elevation in the adjusted mortality risk, as was a 1 g/dL lower serum albumin level.

Merighi, J. R., & Ehlebracht, K. (2004a). Workplace resources, patient caseloads, and job satisfaction of renal social workers in the United States. *Nephrology News & Issues*, 18(4), 58-63.

Merighi, J. R., & Ehlebracht, K. (2004b). Issues for renal social workers in dialysis clinics in the United States. *Nephrology News & Issues*, 18(5), 67-73.

Merighi, J. R., & Ehlebracht, K. (2004c). Unit-based patient services and supportive counseling. *Nephrology News & Issues*, 18(6), 55-60.

Wuerth D, Finklestein SH, Finklestein FO. The identification and treatment of depression in patients maintained on dialysis. *Semin Dial*. 18(2):142-6, 2005.